

US3782028 (Prod: Vanderbilt University Medical Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:48:20

All time stamps listed in this document are displayed in GMT

US3782028

Form: Participant Creation

Data signed: (b) (4) 26 Jan 2021 20:08:44

Generated On: 10 Jun 2021 09:48:20

[Participant ID](#)

US3782028

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

US3782028

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3782028

Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
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

US3782028

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Date of Informed Consent (<i>dd MMM yyyy</i>)	17 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3782028

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3782028

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Were any significant conditions reported?

Yes ☒

No ☐

US3782028

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3782028

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3782028

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1984
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1984
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	JAN 1984
Stop Year (derived)	1984

US3782028

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Condition	UNILATERAL PRIMARY OSTEOARTHRITIS RIGHT HIP
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3782028

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	07:34 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 07:34
Height (xxx.x)	174 cm
Weight (xxx.x)	106.7 kg
BMI (xxx.x)	35.24244 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3782028

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

US3782028

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Date of assessment (dd MMM yyyy) 17 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 1984

Date of surgery unknown False

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

Date of last menstruation unknown False

US3782028

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3782028

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

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

US3782028

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3782028

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 186782

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 ☒

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Height	ND - Not Done
Weight	ND - Not Done

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

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)	19 AUG 2020
Time of assessment (00:00-23:59)	07:25 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 07:25
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

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)	19 AUG 2020
Time of assessment (00:00-23:59)	09:04 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 09:04
Temperature (xxx.x)	96.9 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)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3782028

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

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.

US3782028

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

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) 19 AUG 2020

What was the treatment time? (00:00-23:59) 08:29 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 08:29

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

What was the frequency of the study treatment dosing? ONCE

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

US3782028

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 AUG 2020
Collection time (00:00-23:59)	07:32 (24 HR)
Collection date and time (derived)	19 AUG 2020 07:32

US3782028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:34	19 AUG 2020 07:34
Nasopharyngeal Swab 2	No		

US3782028

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

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

96.9 °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

19 AUG 2020 09:02

PC Open Date & Time

19 AUG 2020 08:49

PC Close Date & Time

19 AUG 2020 11:19

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	19 AUG 2020 19:53
PC Open Date & Time	19 AUG 2020 12:14
PC Close Date & Time	20 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 19:02

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

21 AUG 2020 19:24

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

22 AUG 2020 19:43

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:20

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

97.8 °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

23 AUG 2020 21:03

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 19:34

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:20

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

25 AUG 2020 20:05

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

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

19 AUG 2020 09:03

PC Open Date & Time

19 AUG 2020 08:49

PC Close Date & Time

19 AUG 2020 11:19

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

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

19 AUG 2020 19:53

PC Open Date & Time

19 AUG 2020 12:14

PC Close Date & Time

20 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:20

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

20 AUG 2020 19:02

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:20

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

21 AUG 2020 19:24

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:20

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

22 AUG 2020 19:43

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:20

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

23 AUG 2020 21:03

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:20

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

24 AUG 2020 19:34

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:20

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

25 AUG 2020 20:05

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 09:03
PC Open Date & Time	19 AUG 2020 08:49
PC Close Date & Time	19 AUG 2020 11:19

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 19:54
PC Open Date & Time	19 AUG 2020 12:14
PC Close Date & Time	20 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

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 ☒

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 19:03
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

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 ☒

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 19:25
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

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 ☒

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 19:44
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

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)

52 of 2124

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 21:04
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

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)

54 of 2124

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 19:35
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

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

56 of 2124

EAB) (1725)

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 20:06
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3782028

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782028

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782028

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782028

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782028

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782028

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782028

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

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)	16 SEP 2020
Time of assessment (00:00-23:59)	07:13 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 07:13
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

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)	16 SEP 2020
Time of assessment (00:00-23:59)	08:32 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 08:32
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3782028

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3782028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

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) 16 SEP 2020

What was the treatment time? (00:00-23:59) 08:02 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 08:02

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

US3782028

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 SEP 2020

Collection time (00:00-23:59)

07:22 (24 HR)

Collection date and time (derived)

16 SEP 2020 07:22

US3782028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:28	16 SEP 2020 07:28
Nasopharyngeal Swab 2	No		

US3782028

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

16 SEP 2020 08:33

PC Open Date & Time

16 SEP 2020 08:22

PC Close Date & Time

16 SEP 2020 10:52

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

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

97.6 °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	16 SEP 2020 19:00
PC Open Date & Time	16 SEP 2020 11:47
PC Close Date & Time	17 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

17 SEP 2020 19:32

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

19 SEP 2020 05:17

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:20

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

97.6 °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

19 SEP 2020 20:21

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:20

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

20 SEP 2020 20:03

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:20

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

97.2 °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

21 SEP 2020 21:58

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:20

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

22 SEP 2020 21:40

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

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

16 SEP 2020 08:34

PC Open Date & Time

16 SEP 2020 08:22

PC Close Date & Time

16 SEP 2020 10:52

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

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

16 SEP 2020 19:01

PC Open Date & Time

16 SEP 2020 11:47

PC Close Date & Time

17 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:20

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

17 SEP 2020 19:33

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:20

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

19 SEP 2020 05:17

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:20

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

19 SEP 2020 20:22

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:20

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

20 SEP 2020 20:03

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:20

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

21 SEP 2020 21:58

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:20

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

22 SEP 2020 21:41

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 08:34
PC Open Date & Time	16 SEP 2020 08:22
PC Close Date & Time	16 SEP 2020 10:52

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 19:01
PC Open Date & Time	16 SEP 2020 11:47
PC Close Date & Time	17 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

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 ☒

PRODUCTION RELEASE (v12.003

92 of 2124

EAB) (1725)

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 19:33
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

94 of 2124

EAB) (1725)

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 05:18
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

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 ☒

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 20:22
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

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 ☒

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 20:03
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

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 ☒

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 21:59
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

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 ☒

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 21:41
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3782028

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782028

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782028

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782028

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782028

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782028

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782028

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:08:46

Generated On: 10 Jun 2021 09:48:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3782028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Jan 2021 20:08:46

Generated On: 10 Jun 2021 09:48:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	07:23 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 07:23
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3782028

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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

US3782028

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 OCT 2020

Collection time (00:00-23:59)

07:19 (24 HR)

Collection date and time (derived)

14 OCT 2020 07:19

US3782028

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

21 OCT 2020 07:56:07

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

28 OCT 2020 14:51:32

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 08:00:50

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 07:59:42

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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	23 NOV 2020 07:53:12
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

27 NOV 2020 05:43:12

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

04 DEC 2020 06:04:34

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

11 DEC 2020 09:37:01

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	18 DEC 2020 18:51:58
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 06:11:46

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

01 JAN 2021 13:26:21

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

08 JAN 2021 09:52:26

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

15 JAN 2021 08:50:34

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

22 JAN 2021 07:22:06

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

31 JAN 2021 21:00:49

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

05 FEB 2021 05:42:16

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

12 FEB 2021 14:00:56

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

19 FEB 2021 08:06:27

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	26 FEB 2021 08:00:43
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 05:16:42

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

12 MAR 2021 04:27:06

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

19 MAR 2021 08:07:19

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

26 MAR 2021 04:27:37

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

02 APR 2021 05:01:26

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	09 APR 2021 04:26:15
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

19 APR 2021 05:47:49

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 05:47:58

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 05:06:58

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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"/>

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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°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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission	
Patient Cloud Open Date & Time	04 JUN 2021 00:01
Patient Cloud Close Date & Time	08 JUN 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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"/>

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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"/>

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 334

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

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

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

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

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

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

Patient Cloud Open Date & Time	13 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	17 AUG 2021 23:59
---	-------------------

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

Patient Cloud Open Date & Time	20 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	24 AUG 2021 23:59
---	-------------------

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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°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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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°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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 <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"/>

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission	
Patient Cloud Open Date & Time	17 SEP 2021 00:01
Patient Cloud Close Date & Time	21 SEP 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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"/>

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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"/>

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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"/>

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

Patient Cloud Open Date & Time	22 OCT 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	26 OCT 2021 23:59
---	-------------------

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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"/>

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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°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"/>

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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°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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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"/>

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐ Yes ☐

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission	
Patient Cloud Open Date & Time	24 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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="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"/>

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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°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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission	
Patient Cloud Open Date & Time	01 APR 2022 00:01
Patient Cloud Close Date & Time	05 APR 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 614

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission	
Patient Cloud Open Date & Time	22 APR 2022 00:01
Patient Cloud Close Date & Time	26 APR 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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="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"/>

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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°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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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"/>

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission	
Patient Cloud Open Date & Time	01 JUL 2022 00:01
Patient Cloud Close Date & Time	05 JUL 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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"/>

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐ Yes ☐

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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"/>

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2022 00:01
Patient Cloud Close Date & Time	30 AUG 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission	
Patient Cloud Open Date & Time	16 SEP 2022 00:01
Patient Cloud Close Date & Time	20 SEP 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2022 00:01
Patient Cloud Close Date & Time	04 OCT 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Date and time of submission

Patient Cloud Open Date & Time	21 OCT 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	25 OCT 2022 23:59
---	-------------------

US3782028

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:48:20

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		05 MAR 2021 05:16:51

US3782028

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782028

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782028

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782028

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782028

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782028

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:25:16

Generated On: 10 Jun 2021 09:48:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782028

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:25:16

Generated On: 10 Jun 2021 09:48:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782028

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3782028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

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) _____

US3782028

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 MAR 2021

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

US3782028

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 MAR 2021

Collection time (00:00-23:59)

08:20 (24 HR)

Collection date and time (derived)

18 MAR 2021 08:20

US3782028

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782028

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

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

US3782028

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3782028

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:48:20

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"/>

US3782028

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:48:20

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3782028

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

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3782028

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Date of updated informed consent (dd MMM yyyy) 4 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) 4 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3782028

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

4 JAN 2021

Collection time (00:00-23:59)

10:07 (24 HR)

Collection date and time (derived)

4 JAN 2021 10:07

US3782028

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

4 JAN 2021

Collection time (00:00 - 23:59)

10:08

Collection Date and Time (derived)

4 JAN 2021 10:08

US3782028

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Apr 2021 01:06:15

Generated On: 10 Jun 2021 09:48:20

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 01:06:15

Generated On: 10 Jun 2021 09:48:20

AEID	USA-US125-2021-MRNA-1273-P30 1000002
Adverse event	BILATERAL PULMONARY EMBOLUS
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)	21 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	25 FEB 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	320 of 2124

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 01:06:15

Generated On: 10 Jun 2021 09:48:20

Number of Days in ICU	2
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	NO NEW DIAGNOSTIC EVIDENCE OF RESOLUTION BUT ONGOING NEED FOR ELIQUIS

Narrative

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 01:06:15

Generated On: 10 Jun 2021 09:48:20

SOB STARTED 2/21/21.
SYNCOPE WITH LOC ON 2/22 -
TRANSF TO HOSPITAL VIA EMS
WITH O2 SAT 80%, HR 130'S.
DIAGNOSTICS REVEALED
PULM EMBOLUS BILATERALLY
(S/P THR DEC 2020). SEE
PROCEDURES AND
MEDICATIONS FOR
TREATMENTS. PT
DISCHARGED 2/25 IN STABLE
CONDITION. NOT TESTED FOR
COVID BY CLINIC BUT WAS
TESTED IN HOSPITAL WITH
NEGATIVE RESULT.

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

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

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

Yes ☒

No ☐

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

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication SYNTHROID

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

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)

324 of 2124

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	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 1990
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"/>

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication ALEVE

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 220

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

326 of 2124

EAB) (1725)

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

328 of 2124

EAB) (1725)

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	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)		7 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		7 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication CELEBREX

Prophylaxis Yes ☐
No ☒

Indication RIGHT HIP REPLACEMENT
(POST-OP PAIN)

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

330 of 2124

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	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)	16 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication BABY ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication RIGHT HIP REPLACEMENT
(POST-OP ANTICOAGULATION)

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

332 of 2124

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	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)	16 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication FLEXERIL

Prophylaxis Yes ☐
No ☒

Indication RIGHT HIP REPLACEMENT
(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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

334 of 2124

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	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)		16 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 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"/>

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication SENOKOT (SENNOSIDES 8.6 MG)

Prophylaxis Yes ☒
No ☐

Indication RIGHT HIP REPLACEMENT
(PROPHYLAXIS POST OP
CONSTIPATION)

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

336 of 2124

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	02 JAN 2021	
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"/>

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication RIGHT HIP REPLACEMENT
(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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

338 of 2124

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

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

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication PRILOSEC

Prophylaxis Yes ☒
No ☐

Indication RIGHT HIP REPLACEMENT (GI
PROPHYLAXIS)

Dose per administration 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

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

340 of 2124

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	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)	16 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication RIGHT HIP REPLACEMENT
POST OP PAIN

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

342 of 2124

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	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)	16 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 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"/>

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication SPINAL ANETHESIA

Prophylaxis Yes ☐
No ☒

Indication RIGHT HIP REPLACEMENT

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

344 of 2124

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	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 checked="" type="radio"/>
If route of administration is Other, specify		SPINAL
Start date (dd MMM yyyy)	16 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication HEPARIN

Prophylaxis Yes ☐
No ☒

Indication BILATERAL PULMONARY EMBOLUS

Dose per administration UNK

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

If dose unit is Other, specify UNITS

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 CONTINUOUS VIA TITRATED IV DRIP

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

346 of 2124

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input checked="" type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication EKOS CATHETER PROCEDURE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

348 of 2124

EAB) (1725)

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	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)	22 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	22 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication EKOS CATHETER PROCEDURE

Dose per administration 50

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)

350 of 2124

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	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)		22 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication MIDAZOLAM

Prophylaxis Yes ☐
No ☒

Indication EKOS CATHETER PROCEDURE

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

352 of 2124

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	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)		22 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication LIDOCAINE 1%

Prophylaxis Yes ☐
No ☒

Indication EKOS CATHETER PROCEDURE

Dose per administration 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

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

PRODUCTION RELEASE (v12.003

354 of 2124

EAB) (1725)

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	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)	22 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	22 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication ATEPLASE (CATHOFLO
ACTIVASE)

Prophylaxis Yes ☐
No ☒

Indication EKOS CATHETER PROCEDURE

Dose per administration 0.88

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)

356 of 2124

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	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 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)	22 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication	DEFINITY
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	TRANSTHORACIC ECHOCARDIOGRAM
Dose per administration	2.2
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

358 of 2124

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	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 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)		23 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☒
No ☐

Indication PRESUMPTIVE SEPSIS

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 ☐

PRODUCTION RELEASE (v12.003

360 of 2124

EAB) (1725)

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	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)		22 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☒
No ☐

Indication PRESUMPTIVE SEPSIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

362 of 2124

EAB) (1725)

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	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)		22 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication APIXABAN

Prophylaxis Yes ☐
No ☒

Indication BILATERAL PULMONARY EMBOLUS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

364 of 2124

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	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)	23 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Name of Medication APIXABAN

Prophylaxis Yes ☐
No ☒

Indication BILATERAL PULMONARY EMBOLUS

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

366 of 2124

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3782028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Jan 2021 20:08:45

Generated On: 10 Jun 2021 09:48:20

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3782028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
16 DEC 2020	RIGHT HIP REPLACEMENT	Medical History	
22 FEB 2021	CT ANGIOGRAM CHEST	Adverse Event	
25 FEB 2021	VASCULAR DUPLEX STUDIES	Adverse Event	
22 FEB 2021	EKOS CATHETER	Adverse Event	

US3782028

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:48:20

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

US3782028

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:48:20

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 ☐

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

SAEID	USA-US125-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

SAEID	USA-US125-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	01/MAR/2021 10:54
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

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

SAEID	USA-US125-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	09/MAR/2021 17:23
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

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Apr 2021 01:06:16

Generated On: 10 Jun 2021 09:48:20

SAEID	USA-US125-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/MAR/2021 11:00
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

US3782028 (Prod: Vanderbilt University Medical Center)

US3782028

Form: Participant Creation

Generated On: 10 Jun 2021 09:48:20

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'US3782028'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 12:34:42

US3782028

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:12

US3782028

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 12:34:43

US3782028

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Clinic (Clinic)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:12

US3782028

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered 'SCRN'	System	17 Aug 2020 12:35:12

US3782028

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:20

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 12:34:44

US3782028

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:20

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '66'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:34

US3782028

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:20

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered 'YEARS'	System	17 Aug 2020 12:35:34

US3782028

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:20

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered '66'	System	17 Aug 2020 12:35:50

US3782028

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:20

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Female (F)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:34

US3782028

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:20

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:34

US3782028

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:20

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'I'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:34

US3782028

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:20

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:34

US3782028

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:20

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:34

US3782028

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:20

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:34

US3782028

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:20

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4) (b) (4)	17 Aug 2020 12:35:34

US3782028

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:20

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:34

US3782028

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:20

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:34

US3782028

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:20

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:34

US3782028

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:20

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:34

US3782028

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:20

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '17 Aug 2020'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:50
	(b) (4)	

US3782028

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered 'Aug 2020'	System	17 Aug 2020 12:35:50

US3782028

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered '2020'	System	17 Aug 2020 12:35:50

US3782028

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:20

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Amendment 2 (2)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:50

US3782028

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:50

US3782028

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:20

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:50

US3782028

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:20

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:50

US3782028

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:20

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:50

US3782028

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:20

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 12:34:43

US3782028

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:20

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered 'I'	System	17 Aug 2020 12:35:56

US3782028

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:35:56

US3782028

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:48:20

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:42:46

US3782028

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 13:48:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 13:48:16
Data point term sent to Coder	System	17 Aug 2020 13:46:44
User entered 'HYPOTHYROIDISM'	Carlton Griffin (b) (4)	17 Aug 2020 13:46:10

US3782028

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'UN UNK 1990'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:46:10

US3782028

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:46:10

US3782028

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:46:10

US3782028

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:46:10

US3782028

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:46:10

US3782028

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered 'Jan 1990'	System	17 Aug 2020 13:46:10

US3782028

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered '1990'	System	17 Aug 2020 13:46:10

US3782028

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered empty.	System	17 Aug 2020 13:46:10

US3782028

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered empty.	System	17 Aug 2020 13:46:10

US3782028

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 13:48:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 13:48:17
Data point term sent to Coder	System	17 Aug 2020 13:46:48
User entered 'OSTEOARTHRITIS'	Carlton Griffin (b) (4)	17 Aug 2020 13:46:29

US3782028

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'UN UNK 2010'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:46:29

US3782028

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:46:29

US3782028

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:46:29

US3782028

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:46:29

US3782028

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:46:29

US3782028

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:20

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered 'Jan 2010'	System	17 Aug 2020 13:46:29

US3782028

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered '2010'	System	17 Aug 2020 13:46:29

US3782028

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered empty.	System	17 Aug 2020 13:46:29

US3782028

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered empty.	System	17 Aug 2020 13:46:29

US3782028

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 13:42:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 13:42:20
Data point term sent to Coder	System	05 Oct 2020 13:41:03
User entered 'hysterectomy'	Carlton Griffin (b) (4)	05 Oct 2020 13:40:37

US3782028

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'UN UNK 1984'	(b) (4) Carlton Griffin (b) (4)	05 Oct 2020 13:40:37

US3782028

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	05 Oct 2020 13:40:37

US3782028

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	05 Oct 2020 13:40:37

US3782028

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'UN UNK 1984'	(b) (4) Carlton Griffin (b) (4)	05 Oct 2020 13:40:37

US3782028

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	05 Oct 2020 13:40:37

US3782028

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered 'Jan 1984'	System	05 Oct 2020 13:40:37

US3782028

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered '1984'	System	05 Oct 2020 13:40:37

US3782028

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered 'Jan 1984'	System	05 Oct 2020 13:40:37

US3782028

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered '1984'	System	05 Oct 2020 13:40:37

US3782028

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Dec 2020 11:48:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Dec 2020 11:48:15
Data point term sent to Coder	System	28 Dec 2020 22:04:32
User entered 'unilateral primary osteoarthritis right hip'	Carlton Griffin (b) (4)	28 Dec 2020 22:03:45

US3782028

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'UN Jan 2020'	(b) (4) Carlton Griffin (b) (4)	28 Dec 2020 22:03:45

US3782028

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	28 Dec 2020 22:03:45

US3782028

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	28 Dec 2020 22:03:45

US3782028

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Carlton Griffin (b) (4)	28 Dec 2020 22:03:45

US3782028

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	28 Dec 2020 22:03:45

US3782028

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered 'Jan 2020'	System	28 Dec 2020 22:03:45

US3782028

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered '2020'	System	28 Dec 2020 22:03:45

US3782028

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered empty.	System	28 Dec 2020 22:03:45

US3782028

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered empty.	System	28 Dec 2020 22:03:45

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:38:48

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '17 Aug 2020'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:38:48
	(b) (4)	

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '07:34'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:38:48

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered '17 Aug 2020 07:34'	System	17 Aug 2020 12:38:48

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '174' cm	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:38:48
DataPoint set to visible.	(b) (4) System	17 Aug 2020 12:35:56

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '106.7' kg	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:38:48
DataPoint set to visible.	(b) (4) System	17 Aug 2020 12:35:56

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
Amendment Manager: User entered '35.24244'	System	16 Sep 2020 23:59:18
User entered '35.2'	System	17 Aug 2020 12:38:48
DataPoint set to visible.	System	17 Aug 2020 12:35:56

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered 'kg/m2'	System	17 Aug 2020 12:38:48
DataPoint set to visible.	System	17 Aug 2020 12:35:56

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '98.3' F reason for change: Data Entry Error	(b) (4)	
	Carlton Griffin (b) (4)	17 Aug 2020 13:43:53
User entered missing code ND - Not Done.	(b) (4)	
	Carlton Griffin (b) (4)	17 Aug 2020 12:38:48
	(b) (4)	

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Oral (Oral)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:38:48

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:38:48

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '70' reason for change: Data Entry Error	(b) (4)	
	Carlton Griffin (b) (4)	17 Aug 2020 13:43:53
User entered missing code ND - Not Done.	(b) (4)	
	Carlton Griffin (b) (4)	17 Aug 2020 12:38:48
	(b) (4)	

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered 'bpm'	System	17 Aug 2020 12:38:48

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16' reason for change: Data Entry Error	(b) (4)	
	Carlton Griffin (b) (4)	17 Aug 2020 13:43:53
User entered missing code ND - Not Done.	(b) (4)	
	Carlton Griffin (b) (4)	17 Aug 2020 12:38:48
	(b) (4)	

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered 'breaths/min'	System	17 Aug 2020 12:38:48

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '132' reason for change: Data Entry Error	(b) (4)	
	Carlton Griffin (b) (4)	17 Aug 2020 13:43:53
User entered missing code ND - Not Done.	(b) (4)	
	Carlton Griffin (b) (4)	17 Aug 2020 12:38:48
	(b) (4)	

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered 'mmHg'	System	17 Aug 2020 12:38:48

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '66' reason for change: Data Entry Error	(b) (4)	
	Carlton Griffin (b) (4)	17 Aug 2020 13:43:53
User entered missing code ND - Not Done.	(b) (4)	
	Carlton Griffin (b) (4)	17 Aug 2020 12:38:48
	(b) (4)	

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered 'mmHg'	System	17 Aug 2020 12:38:48

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 08:11:19

US3782028

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 08:11:19

US3782028

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 12:39:02

US3782028

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 22:43:02
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 12:43:09
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	27 Aug 2020 13:51:18
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	25 Aug 2020 13:22:28
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	25 Aug 2020 13:22:28
User entered '17 Aug 2020' reason for change: Data Entry Error	Amber Massey (b) (4) (b) (4)	25 Aug 2020 13:22:28
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	25 Aug 2020 13:22:20
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	25 Aug 2020 13:22:20
User entered '18 Aug 2020' reason for change: Data Entry Error	Amber Massey (b) (4) (b) (4)	25 Aug 2020 13:22:20
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	19 Aug 2020 13:10:08
User entered '17 Aug 2020'	Carlton Griffin (b) (4) (b) (4)	17 Aug 2020 12:39:02

US3782028

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '17 Aug 2020'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:45:26
	(b) (4)	

US3782028

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:20

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:45:26

US3782028

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:20

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
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)	06 Oct 2020 10:03:10
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 13:39:42
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 07:54:38
User entered 'Surgically sterile (SURGICALLY STERILE)'	Carlton Griffin (b) (4) (b) (4)	17 Aug 2020 13:45:26

US3782028

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:20

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:45:26

US3782028

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:20

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'UN UNK 1984'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:45:26

US3782028

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:20

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:45:26

US3782028

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:45:26

US3782028

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:20

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:45:26

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	Carlton Griffin (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	Carlton Griffin (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	Carlton Griffin (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	Carlton Griffin (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	Carlton Griffin (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:44:49
	(b) (4)	

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	Carlton Griffin (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	Carlton Griffin (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'I'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:20

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Carlton Griffin (b) (4)	17 Aug 2020 13:44:49

US3782028

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	17 Aug 2020 12:36:10

US3782028

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '19 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Amber Massey (b) (4)	19 Aug 2020 13:10:08
User entered '17 Aug 2020'	(b) (4)	
	Carlton Griffin (b) (4)	17 Aug 2020 12:36:10
	(b) (4)	

US3782028

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

[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 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Clinic (Clinic)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	17 Aug 2020 12:36:10

US3782028

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'VISIT1'	System	17 Aug 2020 12:36:10

US3782028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User closed query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	19 Aug 2020 13:10:08
Query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	19 Aug 2020 13:10:08
User opened query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Aug 2020 12:49:29
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 12:49:29

US3782028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:20

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:55:44
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:55:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 12:49:29
User entered '186782' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 12:49:29

US3782028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:20

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 12:49:29

US3782028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:20

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 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	19 Aug 2020 13:16:46

US3782028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:20

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 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	19 Aug 2020 13:16:46

US3782028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:20

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	19 Aug 2020 13:16:46

US3782028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:20

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:16:46

US3782028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:20

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:16:46

US3782028

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:20

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	Jenna Caserta (b) (4)	25 Sep 2020 18:20:59
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:22:24
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:34:57

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:20

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User closed query 'Per CDM: The subject was "not" screened, randomized and dosed at the same day but Height and Weight at VID1 were not provided. Kindly provide if available or clarify why these were Not Done.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:45:54
' (Site from DM). Query 'Per CDM: The subject was "not" screened, randomized and dosed at the same day but Height and Weight at VID1 were not provided. Kindly provide if available or clarify why these were Not Done.	Carlton Griffin (b) (4) (b) (4)	02 Nov 2020 20:11:27
' answered with 'at screening date on 17AUG2020, height and weight were obtained. they were not reevaluated on 19AUG2020.' (Site from DM). User opened query 'Per CDM: The subject was "not" screened, randomized and dosed at the same day but Height and Weight at VID1 were not provided. Kindly provide if available or clarify why these were Not Done.	(b) (4), (b) (6)	01 Nov 2020 08:06:04
' (Site from DM). User entered missing code ND - Not Done.	Amber Massey (b) (4) (b) (4)	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:20

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User closed query 'Per CDM: The subject was "not" screened, randomized and dosed at the same day but Height and Weight at VID1 were not provided. Kindly provide if available or clarify why these were Not Done.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:45:54
' (Site from DM). Query 'Per CDM: The subject was "not" screened, randomized and dosed at the same day but Height and Weight at VID1 were not provided. Kindly provide if available or clarify why these were Not Done.	Carlton Griffin (b) (4) (b) (4)	02 Nov 2020 20:11:27
' answered with 'at screening date on 17AUG2020, height and weight were obtained. they were not reevaluated on 19AUG2020.' (Site from DM). User opened query 'Per CDM: The subject was "not" screened, randomized and dosed at the same day but Height and Weight at VID1 were not provided. Kindly provide if available or clarify why these were Not Done.	(b) (4), (b) (6)	01 Nov 2020 08:06:04
' (Site from DM). User entered missing code ND - Not Done.	Amber Massey (b) (4) (b) (4)	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Massey (b) (4)	19 Aug 2020 13:09:52
	(b) (4)	

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	19 Aug 2020 13:10:08
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Aug 2020 13:09:52
User entered '19 Aug 2020'	Amber Massey (b) (4)	19 Aug 2020 13:09:52
	(b) (4)	

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '07:25'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered '19 Aug 2020 07:25'	System	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '98.2' F	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Oral (Oral)'	(b) (4) Amber Massey (b) (4) (b) (4)	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '62'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'bpm'	System	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'breaths/min'	System	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '148'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'mmHg'	System	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '83'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'mmHg'	System	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:20

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User closed query 'Per CDM: The subject was "not" screened, randomized and dosed at the same day but Height and Weight at VID1 were not provided. Kindly provide if available or clarify why these were Not Done.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:45:54
' (Site from DM). Query 'Per CDM: The subject was "not" screened, randomized and dosed at the same day but Height and Weight at VID1 were not provided. Kindly provide if available or clarify why these were Not Done.	Carlton Griffin (b) (4) (b) (4)	02 Nov 2020 20:11:27
' answered with 'at screening date on 17AUG2020, height and weight were obtained. they were not reevaluated on 19AUG2020.' (Site from DM). User opened query 'Per CDM: The subject was "not" screened, randomized and dosed at the same day but Height and Weight at VID1 were not provided. Kindly provide if available or clarify why these were Not Done.	(b) (4), (b) (6)	01 Nov 2020 08:06:04
' (Site from DM). User entered missing code ND - Not Done.	Amber Massey (b) (4) (b) (4)	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:09:52

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Massey (b) (4) (b) (4)	19 Aug 2020 14:16:17

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 14:16:17

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '19 Aug 2020'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 14:16:17

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:08:46
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:55:42
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 minute minimum post-observation period' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 21:47:48
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	19 Aug 2020 14:16:17
User entered '09:04'	Amber Massey (b) (4) (b) (4)	19 Aug 2020 14:16:17

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered '19 Aug 2020 09:04'	System	19 Aug 2020 14:16:17

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '96.9' F	(b) (4) Amber Massey (b) (4)	19 Aug 2020 14:16:17

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Oral (Oral)'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 14:16:17

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Amber Massey (b) (4)	19 Aug 2020 14:16:17

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '66'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 14:16:17

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'bpm'	System	19 Aug 2020 14:16:17

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	20 Aug 2020 21:49:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).		20 Aug 2020 21:49:16
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 21:49:16
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 14:16:17
User entered empty.	Amber Massey (b) (4)	19 Aug 2020 14:16:17
	(b) (4)	

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'breaths/min'	System	20 Aug 2020 21:49:16
User entered empty.	System	19 Aug 2020 14:16:17

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '147'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 14:16:17

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'mmHg'	System	19 Aug 2020 14:16:17

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '85'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 14:16:17

US3782028

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'mmHg'	System	19 Aug 2020 14:16:17

US3782028

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:20

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	(b) (4)	20 Aug 2020 21:43:18
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	20 Aug 2020 21:42:43
User entered 'No (N)'	Amber Massey (b) (4)	19 Aug 2020 13:10:26
	(b) (4)	

US3782028

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Aug 2020 21:43:18
User entered '19 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 21:42:43
User entered empty.	Amber Massey (b) (4) (b) (4)	19 Aug 2020 13:10:26

US3782028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:32:21

US3782028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:32:21

US3782028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

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 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	19 Aug 2020 13:32:21

US3782028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 13:32:21

US3782028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '19 Aug 2020'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:32:21

US3782028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '08:29'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:32:21

US3782028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered '19 Aug 2020 08:29'	System	19 Aug 2020 13:32:21

US3782028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Left Arm (LEFT ARM)'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:32:21

US3782028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'ONCE'	System	19 Aug 2020 13:32:21

US3782028

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 13:32:21

US3782028

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:14:29

US3782028

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '19 Aug 2020'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:14:29

US3782028

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '07:32'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:14:29

US3782028

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered '19 Aug 2020 07:32'	System	19 Aug 2020 13:14:29

US3782028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:48:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '19 Aug 2020'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:14:58

US3782028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amber Massey (b) (4)	19 Aug 2020 13:14:58

US3782028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:14:58

US3782028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '07:34'	(b) (4) Amber Massey (b) (4) (b) (4)	19 Aug 2020 13:14:58

US3782028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered '19 Aug 2020 07:34'	System	19 Aug 2020 13:14:58

US3782028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amber Massey (b) (4)	19 Aug 2020 13:14:58

US3782028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:14:58

US3782028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:14:58

US3782028

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered empty.	System	19 Aug 2020 13:14:58

US3782028

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	19 Aug 2020 13:15:08

US3782028

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered '1'	System	19 Aug 2020 13:15:08

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T09:02:02', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f8113f09-03f1-442b-87f0-403358ce07b2'	System	19 Aug 2020 14:02:30
User entered 'Yes (Y)'	System	19 Aug 2020 14:02:30

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T09:02:12', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f8113f09-03f1-442b-87f0-403358ce07b2'	System	19 Aug 2020 14:02:30
User entered '96.9'	System	19 Aug 2020 14:02:30

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T09:02:18', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f8113f09-03f1-442b-87f0-403358ce07b2'	System	19 Aug 2020 14:02:30
User entered 'No (N)'	System	19 Aug 2020 14:02:30

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T09:02:28', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f8113f09-03f1-442b-87f0-403358ce07b2'	System	19 Aug 2020 14:02:30
User entered '19 Aug 2020 09:02'	System	19 Aug 2020 14:02:30

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '19 Aug 2020 08:49'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '19 Aug 2020 11:19'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T19:53:17', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a0a6fc20-e034-4962-b0b7-ccbe53fb63d9'	System	20 Aug 2020 00:53:41
User entered 'Yes (Y)'	System	20 Aug 2020 00:53:41

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T19:53:27', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a0a6fc20-e034-4962-b0b7-ccbe53fb63d9'	System	20 Aug 2020 00:53:41
User entered '98.2'	System	20 Aug 2020 00:53:41

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T19:53:30', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a0a6fc20-e034-4962-b0b7-ccbe53fb63d9'	System	20 Aug 2020 00:53:41
User entered 'No (N)'	System	20 Aug 2020 00:53:41

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T19:53:38', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a0a6fc20-e034-4962-b0b7-ccbe53fb63d9'	System	20 Aug 2020 00:53:41
User entered '19 Aug 2020 19:53'	System	20 Aug 2020 00:53:41

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '19 Aug 2020 12:14'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 2'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-20T19:01:47', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'bf569b6f-acc-44c7-a58d-e446966cdeec'	System	21 Aug 2020 00:02:05
User entered 'Yes (Y)'	System	21 Aug 2020 00:02:05

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-20T19:01:53', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'bf569b6f-acc-44c7-a58d-e446966cdeec'	System	21 Aug 2020 00:02:05
User entered '98.1'	System	21 Aug 2020 00:02:05

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-20T19:01:56', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'bf569b6f-acc44c7-a58d-e446966cdeec'	System	21 Aug 2020 00:02:05
User entered 'No (N)'	System	21 Aug 2020 00:02:05

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-20T19:02:02', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'bf569b6f-acc-44c7-a58d-e446966cdeec'	System	21 Aug 2020 00:02:05
User entered '20 Aug 2020 19:02'	System	21 Aug 2020 00:02:05

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 3'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-21T19:24:01', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'b03f3e14-ad31-437d-85a7-febe9151319c'	System	22 Aug 2020 00:24:24
User entered 'Yes (Y)'	System	22 Aug 2020 00:24:24

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-21T19:24:08', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'b03f3e14-ad31-437d-85a7-febe9151319c'	System	22 Aug 2020 00:24:24
User entered '98.2'	System	22 Aug 2020 00:24:24

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-21T19:24:11', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'b03f3e14-ad31-437d-85a7-febe9151319c'	System	22 Aug 2020 00:24:24
User entered 'No (N)'	System	22 Aug 2020 00:24:24

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-21T19:24:20', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'b03f3e14-ad31-437d-85a7-febe9151319c'	System	22 Aug 2020 00:24:24
User entered '21 Aug 2020 19:24'	System	22 Aug 2020 00:24:24

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 4'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-22T19:42:57', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '2327c34f-9d5e-438d-84c1-25f907805b0e'	System	23 Aug 2020 00:43:34
User entered 'Yes (Y)'	System	23 Aug 2020 00:43:34

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-22T19:43:13', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '2327c34f-9d5e-438d-84c1-25f907805b0e'	System	23 Aug 2020 00:43:34
User entered '98.0'	System	23 Aug 2020 00:43:34

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-22T19:43:18', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '2327c34f-9d5e-438d-84c1-25f907805b0e'	System	23 Aug 2020 00:43:34
User entered 'No (N)'	System	23 Aug 2020 00:43:34

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-22T19:43:29', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '2327c34f-9d5e-438d-84c1-25f907805b0e'	System	23 Aug 2020 00:43:34
User entered '22 Aug 2020 19:43'	System	23 Aug 2020 00:43:34

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 5'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-23T21:03:08', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '9780655d-ebd1-45ea-9e2d-b9a2e09db746'	System	24 Aug 2020 02:03:27
User entered 'Yes (Y)'	System	24 Aug 2020 02:03:27

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-23T21:03:16', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '9780655d-ebd1-45ea-9e2d-b9a2e09db746'	System	24 Aug 2020 02:03:27
User entered '97.8'	System	24 Aug 2020 02:03:27

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-23T21:03:19', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '9780655d-ebd1-45ea-9e2d-b9a2e09db746'	System	24 Aug 2020 02:03:27
User entered 'No (N)'	System	24 Aug 2020 02:03:27

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-23T21:03:25', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '9780655d-ebd1-45ea-9e2d-b9a2e09db746'	System	24 Aug 2020 02:03:27
User entered '23 Aug 2020 21:03'	System	24 Aug 2020 02:03:27

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 6'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-24T19:34:04', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'b81999d9-5fdf-4b35-ac25-2ed3e3c2d660'	System	25 Aug 2020 00:34:39
User entered 'Yes (Y)'	System	25 Aug 2020 00:34:39

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-24T19:34:25', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'b81999d9-5fdf-4b35-ac25-2ed3e3c2d660'	System	25 Aug 2020 00:34:39
User entered '97.9'	System	25 Aug 2020 00:34:39

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-24T19:34:28', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'b81999d9-5fdf-4b35-ac25-2ed3e3c2d660'	System	25 Aug 2020 00:34:39
User entered 'No (N)'	System	25 Aug 2020 00:34:39

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-24T19:34:34', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'b81999d9-5fdf-4b35-ac25-2ed3e3c2d660'	System	25 Aug 2020 00:34:39
User entered '24 Aug 2020 19:34'	System	25 Aug 2020 00:34:39

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 7'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-25T20:05:20', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '64603230-1d30-49f9-80a4-3e64b2244b96'	System	26 Aug 2020 01:05:37
User entered 'Yes (Y)'	System	26 Aug 2020 01:05:37

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-25T20:05:27', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '64603230-1d30-49f9-80a4-3e64b2244b96'	System	26 Aug 2020 01:05:37
User entered '98.0'	System	26 Aug 2020 01:05:37

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-25T20:05:31', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '64603230-1d30-49f9-80a4-3e64b2244b96'	System	26 Aug 2020 01:05:37
User entered 'No (N)'	System	26 Aug 2020 01:05:37

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-25T20:05:35', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '64603230-1d30-49f9-80a4-3e64b2244b96'	System	26 Aug 2020 01:05:37
User entered '25 Aug 2020 20:05'	System	26 Aug 2020 01:05:37

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T09:02:44', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'de2dd4f2-64b9-4bea-b502-65092bffa468'	System	19 Aug 2020 14:03:13
User entered 'None (1)'	System	19 Aug 2020 14:03:13

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T09:02:48', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'de2dd4f2-64b9-4bea-b502-65092bffa468'	System	19 Aug 2020 14:03:13
User entered 'No (N)'	System	19 Aug 2020 14:03:13

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T09:02:51', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'de2dd4f2-64b9-4bea-b502-65092bffa468'	System	19 Aug 2020 14:03:13
User entered 'No (N)'	System	19 Aug 2020 14:03:13

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T09:03:01', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'de2dd4f2-64b9-4bea-b502-65092bffa468'	System	19 Aug 2020 14:03:13
User entered 'None (1)'	System	19 Aug 2020 14:03:13

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T09:03:07', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'de2dd4f2-64b9-4bea-b502-65092bffa468'	System	19 Aug 2020 14:03:13
User entered '19 Aug 2020 09:03'	System	19 Aug 2020 14:03:13

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '19 Aug 2020 08:49'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '19 Aug 2020 11:19'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T19:53:44', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e9cf46d9-d551-485f-94de-b60bce940323'	System	20 Aug 2020 00:54:02
User entered 'None (1)'	System	20 Aug 2020 00:54:02

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T19:53:47', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e9cf46d9-d551-485f-94de-b60bce940323'	System	20 Aug 2020 00:54:02
User entered 'No (N)'	System	20 Aug 2020 00:54:02

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T19:53:50', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e9cf46d9-d551-485f-94de-b60bce940323'	System	20 Aug 2020 00:54:02
User entered 'No (N)'	System	20 Aug 2020 00:54:02

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T19:53:54', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e9cf46d9-d551-485f-94de-b60bce940323'	System	20 Aug 2020 00:54:02
User entered 'None (1)'	System	20 Aug 2020 00:54:02

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T19:53:58', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e9cf46d9-d551-485f-94de-b60bce940323'	System	20 Aug 2020 00:54:02
User entered '19 Aug 2020 19:53'	System	20 Aug 2020 00:54:02

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '19 Aug 2020 12:14'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 2'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-20T19:02:21', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'ba036035-5c84-4d39-97b9-eb0a06246c63'	System	21 Aug 2020 00:02:46
User entered 'None (1)'	System	21 Aug 2020 00:02:46

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-20T19:02:25', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'ba036035-5c84-4d39-97b9-eb0a06246c63'	System	21 Aug 2020 00:02:46
User entered 'No (N)'	System	21 Aug 2020 00:02:46

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-20T19:02:27', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'ba036035-5c84-4d39-97b9-eb0a06246c63'	System	21 Aug 2020 00:02:46
User entered 'No (N)'	System	21 Aug 2020 00:02:46

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-20T19:02:31', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'ba036035-5c84-4d39-97b9-eb0a06246c63'	System	21 Aug 2020 00:02:46
User entered 'None (1)'	System	21 Aug 2020 00:02:46

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-20T19:02:40', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'ba036035-5c84-4d39-97b9-eb0a06246c63'	System	21 Aug 2020 00:02:46
User entered '20 Aug 2020 19:02'	System	21 Aug 2020 00:02:46

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 3'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-21T19:24:25', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '172ea3be-ce01-45f5-8954-e0735a8c7a32'	System	22 Aug 2020 00:24:42
User entered 'None (1)'	System	22 Aug 2020 00:24:42

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-21T19:24:28', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '172ea3be-ce01-45f5-8954-e0735a8c7a32'	System	22 Aug 2020 00:24:42
User entered 'No (N)'	System	22 Aug 2020 00:24:42

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-21T19:24:30', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '172ea3be-ce01-45f5-8954-e0735a8c7a32'	System	22 Aug 2020 00:24:42
User entered 'No (N)'	System	22 Aug 2020 00:24:42

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-21T19:24:33', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '172ea3be-ce01-45f5-8954-e0735a8c7a32'	System	22 Aug 2020 00:24:42
User entered 'None (1)'	System	22 Aug 2020 00:24:42

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-21T19:24:39', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '172ea3be-ce01-45f5-8954-e0735a8c7a32'	System	22 Aug 2020 00:24:42
User entered '21 Aug 2020 19:24'	System	22 Aug 2020 00:24:42

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 4'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-22T19:43:34', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7a4f336e-5eda-45e7-9ecf-6516fa5080f5'	System	23 Aug 2020 00:43:52
User entered 'None (1)'	System	23 Aug 2020 00:43:52

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-22T19:43:37', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7a4f336e-5eda-45e7-9ecf-6516fa5080f5'	System	23 Aug 2020 00:43:52
User entered 'No (N)'	System	23 Aug 2020 00:43:52

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-22T19:43:40', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7a4f336e-5eda-45e7-9ecf-6516fa5080f5'	System	23 Aug 2020 00:43:52
User entered 'No (N)'	System	23 Aug 2020 00:43:52

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-22T19:43:43', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7a4f336e-5eda-45e7-9ecf-6516fa5080f5'	System	23 Aug 2020 00:43:52
User entered 'None (1)'	System	23 Aug 2020 00:43:52

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-22T19:43:49', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7a4f336e-5eda-45e7-9ecf-6516fa5080f5'	System	23 Aug 2020 00:43:52
User entered '22 Aug 2020 19:43'	System	23 Aug 2020 00:43:52

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 5'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-23T21:03:29', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '8d9f24e9-2aae-4a0b-a4d8-1157003d9ebf'	System	24 Aug 2020 02:03:45
User entered 'None (1)'	System	24 Aug 2020 02:03:45

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-23T21:03:33', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '8d9f24e9-2aae-4a0b-a4d8-1157003d9ebf'	System	24 Aug 2020 02:03:45
User entered 'No (N)'	System	24 Aug 2020 02:03:45

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-23T21:03:36', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '8d9f24e9-2aae-4a0b-a4d8-1157003d9ebf'	System	24 Aug 2020 02:03:45
User entered 'No (N)'	System	24 Aug 2020 02:03:45

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-23T21:03:39', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '8d9f24e9-2aae-4a0b-a4d8-1157003d9ebf'	System	24 Aug 2020 02:03:45
User entered 'None (1)'	System	24 Aug 2020 02:03:45

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-23T21:03:42', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '8d9f24e9-2aae-4a0b-a4d8-1157003d9ebf'	System	24 Aug 2020 02:03:45
User entered '23 Aug 2020 21:03'	System	24 Aug 2020 02:03:45

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 6'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-24T19:34:38', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'cf3db1d3-2738-4202-927c-68aede3cf043'	System	25 Aug 2020 00:34:55
User entered 'None (1)'	System	25 Aug 2020 00:34:55

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-24T19:34:41', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'cf3db1d3-2738-4202-927c-68aede3cf043'	System	25 Aug 2020 00:34:55
User entered 'No (N)'	System	25 Aug 2020 00:34:55

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-24T19:34:43', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'cf3db1d3-2738-4202-927c-68aede3cf043'	System	25 Aug 2020 00:34:55
User entered 'No (N)'	System	25 Aug 2020 00:34:55

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-24T19:34:47', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'cf3db1d3-2738-4202-927c-68aede3cf043'	System	25 Aug 2020 00:34:55
User entered 'None (1)'	System	25 Aug 2020 00:34:55

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-24T19:34:51', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'cf3db1d3-2738-4202-927c-68aede3cf043'	System	25 Aug 2020 00:34:55
User entered '24 Aug 2020 19:34'	System	25 Aug 2020 00:34:55

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 7'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-25T20:05:39', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c14ff1e3-e5b9-4666-ad7b-2177619f27f0'	System	26 Aug 2020 01:05:55
User entered 'None (1)'	System	26 Aug 2020 01:05:55

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-25T20:05:42', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c14ff1e3-e5b9-4666-ad7b-2177619f27f0'	System	26 Aug 2020 01:05:55
User entered 'No (N)'	System	26 Aug 2020 01:05:55

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-25T20:05:45', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c14ff1e3-e5b9-4666-ad7b-2177619f27f0'	System	26 Aug 2020 01:05:55
User entered 'No (N)'	System	26 Aug 2020 01:05:55

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-25T20:05:48', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c14ff1e3-e5b9-4666-ad7b-2177619f27f0'	System	26 Aug 2020 01:05:55
User entered 'None (1)'	System	26 Aug 2020 01:05:55

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-25T20:05:51', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c14ff1e3-e5b9-4666-ad7b-2177619f27f0'	System	26 Aug 2020 01:05:55
User entered '25 Aug 2020 20:05'	System	26 Aug 2020 01:05:55

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T09:03:13', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f9c9b361-f582-4d12-8375-d715ba739a3c'	System	19 Aug 2020 14:03:53
User entered 'None (0)'	System	19 Aug 2020 14:03:53

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T09:03:16', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f9c9b361-f582-4d12-8375-d715ba739a3c'	System	19 Aug 2020 14:03:53
User entered 'None (0)'	System	19 Aug 2020 14:03:53

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T09:03:20', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f9c9b361-f582-4d12-8375-d715ba739a3c'	System	19 Aug 2020 14:03:53
User entered 'None (0)'	System	19 Aug 2020 14:03:53

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T09:03:36', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f9c9b361-f582-4d12-8375-d715ba739a3c'	System	19 Aug 2020 14:03:53
User entered 'None (0)'	System	19 Aug 2020 14:03:53

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T09:03:39', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f9c9b361-f582-4d12-8375-d715ba739a3c'	System	19 Aug 2020 14:03:53
User entered 'None (0)'	System	19 Aug 2020 14:03:53

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T09:03:42', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f9c9b361-f582-4d12-8375-d715ba739a3c'	System	19 Aug 2020 14:03:53
User entered 'None (0)'	System	19 Aug 2020 14:03:53

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T09:03:46', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f9c9b361-f582-4d12-8375-d715ba739a3c'	System	19 Aug 2020 14:03:53
User entered 'No (N)'	System	19 Aug 2020 14:03:53

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T09:03:50', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f9c9b361-f582-4d12-8375-d715ba739a3c'	System	19 Aug 2020 14:03:53
User entered '19 Aug 2020 09:03'	System	19 Aug 2020 14:03:53

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '19 Aug 2020 08:49'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '19 Aug 2020 11:19'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T19:54:04', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a028200c-47c7-4cfd-82ce-bcf4689294aa'	System	20 Aug 2020 00:54:29
User entered 'None (0)'	System	20 Aug 2020 00:54:29

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T19:54:07', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a028200c-47c7-4cfd-82ce-bcf4689294aa'	System	20 Aug 2020 00:54:29
User entered 'None (0)'	System	20 Aug 2020 00:54:29

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T19:54:10', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a028200c-47c7-4cfd-82ce-bcf4689294aa'	System	20 Aug 2020 00:54:29
User entered 'None (0)'	System	20 Aug 2020 00:54:29

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T19:54:13', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a028200c-47c7-4cfd-82ce-bcf4689294aa'	System	20 Aug 2020 00:54:29
User entered 'None (0)'	System	20 Aug 2020 00:54:29

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T19:54:16', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a028200c-47c7-4cfd-82ce-bcf4689294aa'	System	20 Aug 2020 00:54:29
User entered 'None (0)'	System	20 Aug 2020 00:54:29

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T19:54:19', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a028200c-47c7-4cfd-82ce-bcf4689294aa'	System	20 Aug 2020 00:54:29
User entered 'None (0)'	System	20 Aug 2020 00:54:29

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T19:54:22', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a028200c-47c7-4cfd-82ce-bcf4689294aa'	System	20 Aug 2020 00:54:29
User entered 'No (N)'	System	20 Aug 2020 00:54:29

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-19T19:54:26', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a028200c-47c7-4cfd-82ce-bcf4689294aa'	System	20 Aug 2020 00:54:29
User entered '19 Aug 2020 19:54'	System	20 Aug 2020 00:54:29

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '19 Aug 2020 12:14'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 2'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-20T19:02:45', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c5292802-5ad5-40db-bf53-1816c5aca456'	System	21 Aug 2020 00:03:17
User entered 'None (0)'	System	21 Aug 2020 00:03:17

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-20T19:02:48', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c5292802-5ad5-40db-bf53-1816c5aca456'	System	21 Aug 2020 00:03:17
User entered 'None (0)'	System	21 Aug 2020 00:03:17

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-20T19:02:52', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c5292802-5ad5-40db-bf53-1816c5aca456'	System	21 Aug 2020 00:03:17
User entered 'None (0)'	System	21 Aug 2020 00:03:17

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-20T19:02:55', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c5292802-5ad5-40db-bf53-1816c5aca456'	System	21 Aug 2020 00:03:17
User entered 'None (0)'	System	21 Aug 2020 00:03:17

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-20T19:02:58', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c5292802-5ad5-40db-bf53-1816c5aca456'	System	21 Aug 2020 00:03:17
User entered 'None (0)'	System	21 Aug 2020 00:03:17

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-20T19:03:01', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c5292802-5ad5-40db-bf53-1816c5aca456'	System	21 Aug 2020 00:03:17
User entered 'None (0)'	System	21 Aug 2020 00:03:17

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-20T19:03:04', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c5292802-5ad5-40db-bf53-1816c5aca456'	System	21 Aug 2020 00:03:17
User entered 'No (N)'	System	21 Aug 2020 00:03:17

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-20T19:03:11', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c5292802-5ad5-40db-bf53-1816c5aca456'	System	21 Aug 2020 00:03:17
User entered '20 Aug 2020 19:03'	System	21 Aug 2020 00:03:17

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 3'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-21T19:24:45', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7e0c2e2f-6f38-4343-b282-ade4e35c49d5'	System	22 Aug 2020 00:25:13
User entered 'None (0)'	System	22 Aug 2020 00:25:13

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-21T19:24:48', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7e0c2e2f-6f38-4343-b282-ade4e35c49d5'	System	22 Aug 2020 00:25:13
User entered 'None (0)'	System	22 Aug 2020 00:25:13

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-21T19:24:50', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7e0c2e2f-6f38-4343-b282-ade4e35c49d5'	System	22 Aug 2020 00:25:13
User entered 'None (0)'	System	22 Aug 2020 00:25:13

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-21T19:24:53', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7e0c2e2f-6f38-4343-b282-ade4e35c49d5'	System	22 Aug 2020 00:25:13
User entered 'None (0)'	System	22 Aug 2020 00:25:13

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-21T19:24:56', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7e0c2e2f-6f38-4343-b282-ade4e35c49d5'	System	22 Aug 2020 00:25:13
User entered 'None (0)'	System	22 Aug 2020 00:25:13

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-21T19:24:59', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7e0c2e2f-6f38-4343-b282-ade4e35c49d5'	System	22 Aug 2020 00:25:13
User entered 'None (0)'	System	22 Aug 2020 00:25:13

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-21T19:25:04', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7e0c2e2f-6f38-4343-b282-ade4e35c49d5'	System	22 Aug 2020 00:25:13
User entered 'No (N)'	System	22 Aug 2020 00:25:13

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-21T19:25:11', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7e0c2e2f-6f38-4343-b282-ade4e35c49d5'	System	22 Aug 2020 00:25:13
User entered '21 Aug 2020 19:25'	System	22 Aug 2020 00:25:13

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 4'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-22T19:43:53', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '5f39b246-1d00-4650-b7f9-1a0ee8a17fe1'	System	23 Aug 2020 00:44:27
User entered 'None (0)'	System	23 Aug 2020 00:44:27

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-22T19:43:57', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '5f39b246-1d00-4650-b7f9-1a0ee8a17fe1'	System	23 Aug 2020 00:44:27
User entered 'None (0)'	System	23 Aug 2020 00:44:27

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-22T19:44:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '5f39b246-1d00-4650-b7f9-1a0ee8a17fe1'	System	23 Aug 2020 00:44:27
User entered 'None (0)'	System	23 Aug 2020 00:44:27

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-22T19:44:03', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '5f39b246-1d00-4650-b7f9-1a0ee8a17fe1'	System	23 Aug 2020 00:44:27
User entered 'None (0)'	System	23 Aug 2020 00:44:27

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-22T19:44:07', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '5f39b246-1d00-4650-b7f9-1a0ee8a17fe1'	System	23 Aug 2020 00:44:27
User entered 'None (0)'	System	23 Aug 2020 00:44:27

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-22T19:44:09', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '5f39b246-1d00-4650-b7f9-1a0ee8a17fe1'	System	23 Aug 2020 00:44:27
User entered 'None (0)'	System	23 Aug 2020 00:44:27

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-22T19:44:17', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '5f39b246-1d00-4650-b7f9-1a0ee8a17fe1'	System	23 Aug 2020 00:44:27
User entered 'No (N)'	System	23 Aug 2020 00:44:27

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-22T19:44:25', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '5f39b246-1d00-4650-b7f9-1a0ee8a17fe1'	System	23 Aug 2020 00:44:27
User entered '22 Aug 2020 19:44'	System	23 Aug 2020 00:44:27

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 5'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-23T21:03:47', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f68c9133-2c15-45a7-9e87-23a308f899d4'	System	24 Aug 2020 02:04:12
User entered 'None (0)'	System	24 Aug 2020 02:04:12

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-23T21:03:50', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f68c9133-2c15-45a7-9e87-23a308f899d4'	System	24 Aug 2020 02:04:12
User entered 'None (0)'	System	24 Aug 2020 02:04:12

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-23T21:03:53', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f68c9133-2c15-45a7-9e87-23a308f899d4'	System	24 Aug 2020 02:04:12
User entered 'None (0)'	System	24 Aug 2020 02:04:12

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-23T21:03:56', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f68c9133-2c15-45a7-9e87-23a308f899d4'	System	24 Aug 2020 02:04:12
User entered 'None (0)'	System	24 Aug 2020 02:04:12

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-23T21:03:59', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f68c9133-2c15-45a7-9e87-23a308f899d4'	System	24 Aug 2020 02:04:12
User entered 'None (0)'	System	24 Aug 2020 02:04:12

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-23T21:04:01', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f68c9133-2c15-45a7-9e87-23a308f899d4'	System	24 Aug 2020 02:04:12
User entered 'None (0)'	System	24 Aug 2020 02:04:12

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-23T21:04:04', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f68c9133-2c15-45a7-9e87-23a308f899d4'	System	24 Aug 2020 02:04:12
User entered 'No (N)'	System	24 Aug 2020 02:04:12

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-23T21:04:08', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f68c9133-2c15-45a7-9e87-23a308f899d4'	System	24 Aug 2020 02:04:12
User entered '23 Aug 2020 21:04'	System	24 Aug 2020 02:04:12

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 6'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-24T19:34:55', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e4ebddf5-4bb8-4f9f-a556-08532c40ef71'	System	25 Aug 2020 00:35:16
User entered 'None (0)'	System	25 Aug 2020 00:35:16

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-24T19:34:57', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e4ebddf5-4bb8-4f9f-a556-08532c40ef71'	System	25 Aug 2020 00:35:16
User entered 'None (0)'	System	25 Aug 2020 00:35:16

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-24T19:35:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e4ebddf5-4bb8-4f9f-a556-08532c40ef71'	System	25 Aug 2020 00:35:16
User entered 'None (0)'	System	25 Aug 2020 00:35:16

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-24T19:35:02', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e4ebddf5-4bb8-4f9f-a556-08532c40ef71'	System	25 Aug 2020 00:35:16
User entered 'None (0)'	System	25 Aug 2020 00:35:16

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-24T19:35:04', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e4ebddf5-4bb8-4f9f-a556-08532c40ef71'	System	25 Aug 2020 00:35:16
User entered 'None (0)'	System	25 Aug 2020 00:35:16

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-24T19:35:06', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e4ebddf5-4bb8-4f9f-a556-08532c40ef71'	System	25 Aug 2020 00:35:16
User entered 'None (0)'	System	25 Aug 2020 00:35:16

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-24T19:35:09', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e4ebddf5-4bb8-4f9f-a556-08532c40ef71'	System	25 Aug 2020 00:35:16
User entered 'No (N)'	System	25 Aug 2020 00:35:16

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-24T19:35:12', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e4ebddf5-4bb8-4f9f-a556-08532c40ef71'	System	25 Aug 2020 00:35:16
User entered '24 Aug 2020 19:35'	System	25 Aug 2020 00:35:16

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 7'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-25T20:05:55', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'aa7d9929-a65d-4d89-8429-3a5cd026f4e9'	System	26 Aug 2020 01:06:19
User entered 'None (0)'	System	26 Aug 2020 01:06:19

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-25T20:05:58', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'aa7d9929-a65d-4d89-8429-3a5cd026f4e9'	System	26 Aug 2020 01:06:19
User entered 'None (0)'	System	26 Aug 2020 01:06:19

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-25T20:06:01', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'aa7d9929-a65d-4d89-8429-3a5cd026f4e9'	System	26 Aug 2020 01:06:19
User entered 'None (0)'	System	26 Aug 2020 01:06:19

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-25T20:06:03', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'aa7d9929-a65d-4d89-8429-3a5cd026f4e9'	System	26 Aug 2020 01:06:19
User entered 'None (0)'	System	26 Aug 2020 01:06:19

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-25T20:06:07', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'aa7d9929-a65d-4d89-8429-3a5cd026f4e9'	System	26 Aug 2020 01:06:19
User entered 'None (0)'	System	26 Aug 2020 01:06:19

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-25T20:06:09', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'aa7d9929-a65d-4d89-8429-3a5cd026f4e9'	System	26 Aug 2020 01:06:19
User entered 'None (0)'	System	26 Aug 2020 01:06:19

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-25T20:06:13', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'aa7d9929-a65d-4d89-8429-3a5cd026f4e9'	System	26 Aug 2020 01:06:19
User entered 'No (N)'	System	26 Aug 2020 01:06:19

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-08-25T20:06:16', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'aa7d9929-a65d-4d89-8429-3a5cd026f4e9'	System	26 Aug 2020 01:06:19
User entered '25 Aug 2020 20:06'	System	26 Aug 2020 01:06:19

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 13:32:21

US3782028

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:21:27

US3782028

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:21:27

US3782028

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:21:27

US3782028

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:21:27

US3782028

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:21:35

US3782028

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'I'	System	26 Aug 2020 15:21:35

US3782028

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	02 Sep 2020 13:19:53

US3782028

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '02 Sep 2020'	(b) (4) Amber Massey (b) (4)	02 Sep 2020 13:19:53

US3782028

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amber Massey (b) (4)	02 Sep 2020 13:19:53

US3782028

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	02 Sep 2020 13:19:53

US3782028

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	02 Sep 2020 13:19:58

US3782028

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'I'	System	02 Sep 2020 13:19:58

US3782028

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 14:05:32

US3782028

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 14:05:32

US3782028

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 14:05:32

US3782028

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 14:05:32

US3782028

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 14:05:39

US3782028

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'I'	System	09 Sep 2020 14:05:39

US3782028

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	16 Sep 2020 12:43:09

US3782028

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16 Sep 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	16 Sep 2020 12:43:09

US3782028

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

[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 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Clinic (Clinic)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	16 Sep 2020 12:43:09

US3782028

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'VISIT2'	System	16 Sep 2020 12:43:09

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User accepted default value 'Pre-Dose (PREDOSE)'	Carlton Griffin (b) (4) (b) (4)	16 Sep 2020 12:45:38

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	16 Sep 2020 12:45:38

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16 Sep 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	16 Sep 2020 12:45:38

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '07:13'	(b) (4) Carlton Griffin (b) (4) (b) (4)	16 Sep 2020 12:45:38

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered '16 Sep 2020 07:13'	System	16 Sep 2020 12:45:38

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '97.9' F	Carlton Griffin (b) (4)	16 Sep 2020 12:45:38

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Oral (Oral)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	16 Sep 2020 12:45:38

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Carlton Griffin (b) (4)	16 Sep 2020 12:45:38

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '74'	Carlton Griffin (b) (4)	16 Sep 2020 12:45:38

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'bpm'	System	16 Sep 2020 12:45:38

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16'	Carlton Griffin (b) (4)	16 Sep 2020 12:45:38

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'breaths/min'	System	16 Sep 2020 12:45:38

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '119'	Carlton Griffin (b) (4)	16 Sep 2020 12:45:38

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'mmHg'	System	16 Sep 2020 12:45:38

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '70'	Carlton Griffin (b) (4)	16 Sep 2020 12:45:38

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'mmHg'	System	16 Sep 2020 12:45:38

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User accepted default value 'Post-Dose (POSTDOSE)'	Carlton Griffin (b) (4) (b) (4)	16 Sep 2020 13:32:59

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	16 Sep 2020 13:32:59

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16 Sep 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	16 Sep 2020 13:32:59

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '08:32'	(b) (4) Carlton Griffin (b) (4) (b) (4)	16 Sep 2020 13:32:59

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered '16 Sep 2020 08:32'	System	16 Sep 2020 13:32:59

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '98.8' F	Carlton Griffin (b) (4)	16 Sep 2020 13:32:59

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Oral (Oral)'	(b) (4) Carlton Griffin (b) (4)	16 Sep 2020 13:32:59

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Carlton Griffin (b) (4)	16 Sep 2020 13:32:59

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '62'	Carlton Griffin (b) (4)	16 Sep 2020 13:32:59

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'bpm'	System	16 Sep 2020 13:32:59

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16'	Carlton Griffin (b) (4)	16 Sep 2020 13:32:59

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'breaths/min'	System	16 Sep 2020 13:32:59

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '134'	(b) (4) Carlton Griffin (b) (4)	16 Sep 2020 13:32:59

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'mmHg'	System	16 Sep 2020 13:32:59

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '66'	(b) (4) Carlton Griffin (b) (4) (b) (4)	16 Sep 2020 13:32:59

US3782028

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'mmHg'	System	16 Sep 2020 13:32:59

US3782028

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	16 Sep 2020 12:43:37

US3782028

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16 Sep 2020'	Carlton Griffin (b) (4)	16 Sep 2020 12:43:37

US3782028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	16 Sep 2020 13:04:16

US3782028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Carlton Griffin (b) (4)	16 Sep 2020 13:04:16

US3782028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

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 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	Carlton Griffin (b) (4)	16 Sep 2020 13:04:16

US3782028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 13:04:16

US3782028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16 Sep 2020'	Carlton Griffin (b) (4)	16 Sep 2020 13:04:16

US3782028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '08:02'	(b) (4) Carlton Griffin (b) (4)	16 Sep 2020 13:04:16

US3782028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered '16 Sep 2020 08:02'	System	16 Sep 2020 13:04:16

US3782028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Left Arm (LEFT ARM)'	Carlton Griffin (b) (4)	16 Sep 2020 13:04:16

US3782028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'ONCE'	System	16 Sep 2020 13:04:16

US3782028

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 13:04:16

US3782028

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	16 Sep 2020 12:43:55

US3782028

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16 Sep 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	16 Sep 2020 12:43:55

US3782028

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '07:22'	(b) (4) Carlton Griffin (b) (4) (b) (4)	16 Sep 2020 12:43:55

US3782028

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered '16 Sep 2020 07:22'	System	16 Sep 2020 12:43:55

US3782028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:48:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16 Sep 2020'	(b) (4) Carlton Griffin (b) (4)	16 Sep 2020 12:44:08

US3782028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Carlton Griffin (b) (4) (b) (4)	16 Sep 2020 12:44:08

US3782028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	16 Sep 2020 12:44:08

US3782028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '07:28'	(b) (4) Carlton Griffin (b) (4)	16 Sep 2020 12:44:08

US3782028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered '16 Sep 2020 07:28'	System	16 Sep 2020 12:44:08

US3782028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Carlton Griffin (b) (4) (b) (4)	16 Sep 2020 12:44:08

US3782028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	16 Sep 2020 12:44:08

US3782028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Carlton Griffin (b) (4)	16 Sep 2020 12:44:08

US3782028

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered empty.	System	16 Sep 2020 12:44:08

US3782028

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	16 Sep 2020 12:45:06

US3782028

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered '1'	System	16 Sep 2020 12:45:06

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T08:33:30', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'd5a204be-f193-42f9-b3b3-f9449886e6a2'	System	16 Sep 2020 13:33:52
User entered 'Yes (Y)'	System	16 Sep 2020 13:33:52

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T08:33:37', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'd5a204be-f193-42f9-b3b3-f9449886e6a2'	System	16 Sep 2020 13:33:52
User entered '98.8'	System	16 Sep 2020 13:33:52

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T08:33:41', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'd5a204be-f193-42f9-b3b3-f9449886e6a2'	System	16 Sep 2020 13:33:52
User entered 'No (N)'	System	16 Sep 2020 13:33:52

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T08:33:48', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'd5a204be-f193-42f9-b3b3-f9449886e6a2'	System	16 Sep 2020 13:33:52
User entered '16 Sep 2020 08:33'	System	16 Sep 2020 13:33:52

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '16 Sep 2020 08:22'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '16 Sep 2020 10:52'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T19:00:41', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f18b7792-a4b3-46b5-b1be-a8d4bc3541d2'	System	17 Sep 2020 00:01:02
User entered 'Yes (Y)'	System	17 Sep 2020 00:01:02

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T19:00:49', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f18b7792-a4b3-46b5-b1be-a8d4bc3541d2'	System	17 Sep 2020 00:01:02
User entered '97.6'	System	17 Sep 2020 00:01:02

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T19:00:52', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f18b7792-a4b3-46b5-b1be-a8d4bc3541d2'	System	17 Sep 2020 00:01:02
User entered 'No (N)'	System	17 Sep 2020 00:01:02

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T19:00:56', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f18b7792-a4b3-46b5-b1be-a8d4bc3541d2'	System	17 Sep 2020 00:01:02
User entered '16 Sep 2020 19:00'	System	17 Sep 2020 00:01:02

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '16 Sep 2020 11:47'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 2'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-17T19:32:10', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '4a015dc0-e989-4e60-ab03-9bcab4cdd04f'	System	18 Sep 2020 00:32:40
User entered 'Yes (Y)'	System	18 Sep 2020 00:32:40

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-17T19:32:16', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '4a015dc0-e989-4e60-ab03-9bcab4cdd04f'	System	18 Sep 2020 00:32:40
User entered '98.2'	System	18 Sep 2020 00:32:40

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-17T19:32:19', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '4a015dc0-e989-4e60-ab03-9bcab4cdd04f'	System	18 Sep 2020 00:32:40
User entered 'No (N)'	System	18 Sep 2020 00:32:40

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-17T19:32:35', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '4a015dc0-e989-4e60-ab03-9bcab4cdd04f'	System	18 Sep 2020 00:32:40
User entered '17 Sep 2020 19:32'	System	18 Sep 2020 00:32:40

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 3'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T05:16:49', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '36d69ab1-0f25-4a15-8dcf-87c33146a128'	System	19 Sep 2020 10:17:16
User entered 'Yes (Y)'	System	19 Sep 2020 10:17:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T05:17:01', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '36d69ab1-0f25-4a15-8dcf-87c33146a128'	System	19 Sep 2020 10:17:16
User entered '98.2'	System	19 Sep 2020 10:17:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T05:17:05', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '36d69ab1-0f25-4a15-8dcf-87c33146a128'	System	19 Sep 2020 10:17:16
User entered 'No (N)'	System	19 Sep 2020 10:17:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T05:17:14', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '36d69ab1-0f25-4a15-8dcf-87c33146a128'	System	19 Sep 2020 10:17:16
User entered '19 Sep 2020 05:17'	System	19 Sep 2020 10:17:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 4'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T20:21:30', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '34160e74-695f-4441-b14e-74f0b3db0051'	System	20 Sep 2020 01:21:50
User entered 'Yes (Y)'	System	20 Sep 2020 01:21:50

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T20:21:39', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '34160e74-695f-4441-b14e-74f0b3db0051'	System	20 Sep 2020 01:21:50
User entered '97.6'	System	20 Sep 2020 01:21:50

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T20:21:42', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '34160e74-695f-4441-b14e-74f0b3db0051'	System	20 Sep 2020 01:21:50
User entered 'No (N)'	System	20 Sep 2020 01:21:50

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T20:21:48', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '34160e74-695f-4441-b14e-74f0b3db0051'	System	20 Sep 2020 01:21:50
User entered '19 Sep 2020 20:21'	System	20 Sep 2020 01:21:50

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 5'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-20T20:02:58', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '57f61710-e068-42ae-866f-ccb8ff61f80c'	System	21 Sep 2020 01:03:13
User entered 'Yes (Y)'	System	21 Sep 2020 01:03:13

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-20T20:03:03', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '57f61710-e068-42ae-866f-ccb8ff61f80c'	System	21 Sep 2020 01:03:13
User entered '97.9'	System	21 Sep 2020 01:03:13

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-20T20:03:07', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '57f61710-e068-42ae-866f-ccb8ff61f80c'	System	21 Sep 2020 01:03:13
User entered 'No (N)'	System	21 Sep 2020 01:03:13

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-20T20:03:12', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '57f61710-e068-42ae-866f-ccb8ff61f80c'	System	21 Sep 2020 01:03:13
User entered '20 Sep 2020 20:03'	System	21 Sep 2020 01:03:13

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 6'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-21T21:58:25', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '178d898e-2a63-482d-a30f-ba32008ef186'	System	22 Sep 2020 02:58:39
User entered 'Yes (Y)'	System	22 Sep 2020 02:58:39

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-21T21:58:31', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '178d898e-2a63-482d-a30f-ba32008ef186'	System	22 Sep 2020 02:58:39
User entered '97.2'	System	22 Sep 2020 02:58:39

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-21T21:58:35', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '178d898e-2a63-482d-a30f-ba32008ef186'	System	22 Sep 2020 02:58:39
User entered 'No (N)'	System	22 Sep 2020 02:58:39

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-21T21:58:39', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '178d898e-2a63-482d-a30f-ba32008ef186'	System	22 Sep 2020 02:58:39
User entered '21 Sep 2020 21:58'	System	22 Sep 2020 02:58:39

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 7'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-22T21:40:35', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'eeb91ccf-70cb-437e-a62b-cfd4d3feffab'	System	23 Sep 2020 02:40:52
User entered 'Yes (Y)'	System	23 Sep 2020 02:40:52

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-22T21:40:40', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'eeb91ccf-70cb-437e-a62b-cfd4d3feffab'	System	23 Sep 2020 02:40:52
User entered '97.4'	System	23 Sep 2020 02:40:52

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-22T21:40:43', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'eeb91ccf-70cb-437e-a62b-cfd4d3feffab'	System	23 Sep 2020 02:40:52
User entered 'No (N)'	System	23 Sep 2020 02:40:52

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-22T21:40:49', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'eeb91ccf-70cb-437e-a62b-cfd4d3feffab'	System	23 Sep 2020 02:40:52
User entered '22 Sep 2020 21:40'	System	23 Sep 2020 02:40:52

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T08:33:54', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '8afc0bd5-6536-4bff-8b60-ecd33b8b06ad'	System	16 Sep 2020 13:34:14
User entered 'None (1)'	System	16 Sep 2020 13:34:14

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T08:33:59', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '8afc0bd5-6536-4bff-8b60-ecd33b8b06ad'	System	16 Sep 2020 13:34:14
User entered 'No (N)'	System	16 Sep 2020 13:34:14

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T08:34:02', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '8afc0bd5-6536-4bff-8b60-ecd33b8b06ad'	System	16 Sep 2020 13:34:14
User entered 'No (N)'	System	16 Sep 2020 13:34:14

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T08:34:05', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '8afc0bd5-6536-4bff-8b60-ecd33b8b06ad'	System	16 Sep 2020 13:34:14
User entered 'None (1)'	System	16 Sep 2020 13:34:14

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T08:34:11', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '8afc0bd5-6536-4bff-8b60-ecd33b8b06ad'	System	16 Sep 2020 13:34:14
User entered '16 Sep 2020 08:34'	System	16 Sep 2020 13:34:14

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '16 Sep 2020 08:22'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '16 Sep 2020 10:52'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T19:01:01', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '53d462a1-7b84-4ebd-b973-574eed500b9c'	System	17 Sep 2020 00:01:27
User entered 'None (1)'	System	17 Sep 2020 00:01:27

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T19:01:04', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '53d462a1-7b84-4ebd-b973-574eed500b9c'	System	17 Sep 2020 00:01:27
User entered 'No (N)'	System	17 Sep 2020 00:01:27

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T19:01:08', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '53d462a1-7b84-4ebd-b973-574eed500b9c'	System	17 Sep 2020 00:01:27
User entered 'No (N)'	System	17 Sep 2020 00:01:27

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T19:01:12', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '53d462a1-7b84-4ebd-b973-574eed500b9c'	System	17 Sep 2020 00:01:27
User entered 'None (1)'	System	17 Sep 2020 00:01:27

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T19:01:18', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '53d462a1-7b84-4ebd-b973-574eed500b9c'	System	17 Sep 2020 00:01:27
User entered '16 Sep 2020 19:01'	System	17 Sep 2020 00:01:27

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '16 Sep 2020 11:47'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 2'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-17T19:32:55', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c5a1cfd6-89ec-41ff-9580-a1f97c3b327e'	System	18 Sep 2020 00:33:18
User entered 'None (1)'	System	18 Sep 2020 00:33:18

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-17T19:32:58', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c5a1cfd6-89ec-41ff-9580-a1f97c3b327e'	System	18 Sep 2020 00:33:18
User entered 'No (N)'	System	18 Sep 2020 00:33:18

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-17T19:33:03', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c5a1cfd6-89ec-41ff-9580-a1f97c3b327e'	System	18 Sep 2020 00:33:18
User entered 'No (N)'	System	18 Sep 2020 00:33:18

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-17T19:33:09', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c5a1cfd6-89ec-41ff-9580-a1f97c3b327e'	System	18 Sep 2020 00:33:18
User entered 'None (1)'	System	18 Sep 2020 00:33:18

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-17T19:33:15', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c5a1cfd6-89ec-41ff-9580-a1f97c3b327e'	System	18 Sep 2020 00:33:18
User entered '17 Sep 2020 19:33'	System	18 Sep 2020 00:33:18

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 3'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T05:17:19', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '36596a29-cdfc-46c6-b442-32afbe9de160'	System	19 Sep 2020 10:17:42
User entered 'None (1)'	System	19 Sep 2020 10:17:42

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T05:17:24', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '36596a29-cdfc-46c6-b442-32afbe9de160'	System	19 Sep 2020 10:17:42
User entered 'No (N)'	System	19 Sep 2020 10:17:42

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T05:17:28', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '36596a29-cdfc-46c6-b442-32afbe9de160'	System	19 Sep 2020 10:17:42
User entered 'No (N)'	System	19 Sep 2020 10:17:42

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T05:17:31', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '36596a29-cdfc-46c6-b442-32afbe9de160'	System	19 Sep 2020 10:17:42
User entered 'None (1)'	System	19 Sep 2020 10:17:42

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T05:17:38', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '36596a29-cdfc-46c6-b442-32afbe9de160'	System	19 Sep 2020 10:17:42
User entered '19 Sep 2020 05:17'	System	19 Sep 2020 10:17:42

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 4'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T20:21:53', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'd89a8276-a531-4699-9172-ac7591efd02c'	System	20 Sep 2020 01:22:11
User entered 'None (1)'	System	20 Sep 2020 01:22:11

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T20:21:57', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'd89a8276-a531-4699-9172-ac7591efd02c'	System	20 Sep 2020 01:22:11
User entered 'No (N)'	System	20 Sep 2020 01:22:11

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T20:22:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'd89a8276-a531-4699-9172-ac7591efd02c'	System	20 Sep 2020 01:22:11
User entered 'No (N)'	System	20 Sep 2020 01:22:11

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T20:22:04', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'd89a8276-a531-4699-9172-ac7591efd02c'	System	20 Sep 2020 01:22:11
User entered 'None (1)'	System	20 Sep 2020 01:22:11

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T20:22:09', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'd89a8276-a531-4699-9172-ac7591efd02c'	System	20 Sep 2020 01:22:11
User entered '19 Sep 2020 20:22'	System	20 Sep 2020 01:22:11

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 5'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-20T20:03:19', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a607a7c6-1293-4973-976d-66d49db05962'	System	21 Sep 2020 01:03:38
User entered 'None (1)'	System	21 Sep 2020 01:03:38

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-20T20:03:22', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a607a7c6-1293-4973-976d-66d49db05962'	System	21 Sep 2020 01:03:38
User entered 'No (N)'	System	21 Sep 2020 01:03:38

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-20T20:03:25', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a607a7c6-1293-4973-976d-66d49db05962'	System	21 Sep 2020 01:03:38
User entered 'No (N)'	System	21 Sep 2020 01:03:38

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-20T20:03:28', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a607a7c6-1293-4973-976d-66d49db05962'	System	21 Sep 2020 01:03:38
User entered 'None (1)'	System	21 Sep 2020 01:03:38

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-20T20:03:32', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a607a7c6-1293-4973-976d-66d49db05962'	System	21 Sep 2020 01:03:38
User entered '20 Sep 2020 20:03'	System	21 Sep 2020 01:03:38

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 6'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-21T21:58:44', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7162ec4c-aa56-488f-a780-361368a3d956'	System	22 Sep 2020 02:58:59
User entered 'None (1)'	System	22 Sep 2020 02:58:59

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-21T21:58:47', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7162ec4c-aa56-488f-a780-361368a3d956'	System	22 Sep 2020 02:58:59
User entered 'No (N)'	System	22 Sep 2020 02:58:59

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-21T21:58:50', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7162ec4c-aa56-488f-a780-361368a3d956'	System	22 Sep 2020 02:58:59
User entered 'No (N)'	System	22 Sep 2020 02:58:59

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-21T21:58:54', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7162ec4c-aa56-488f-a780-361368a3d956'	System	22 Sep 2020 02:58:59
User entered 'None (1)'	System	22 Sep 2020 02:58:59

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-21T21:58:57', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7162ec4c-aa56-488f-a780-361368a3d956'	System	22 Sep 2020 02:58:59
User entered '21 Sep 2020 21:58'	System	22 Sep 2020 02:58:59

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 7'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-22T21:40:53', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '49db4c59-5292-4a4b-b442-1eed056c0f57'	System	23 Sep 2020 02:41:09
User entered 'None (1)'	System	23 Sep 2020 02:41:09

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-22T21:40:56', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '49db4c59-5292-4a4b-b442-1eed056c0f57'	System	23 Sep 2020 02:41:09
User entered 'No (N)'	System	23 Sep 2020 02:41:09

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-22T21:40:58', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '49db4c59-5292-4a4b-b442-1eed056c0f57'	System	23 Sep 2020 02:41:09
User entered 'No (N)'	System	23 Sep 2020 02:41:09

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:20

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-22T21:41:01', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '49db4c59-5292-4a4b-b442-1eed056c0f57'	System	23 Sep 2020 02:41:09
User entered 'None (1)'	System	23 Sep 2020 02:41:09

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-22T21:41:04', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '49db4c59-5292-4a4b-b442-1eed056c0f57'	System	23 Sep 2020 02:41:09
User entered '22 Sep 2020 21:41'	System	23 Sep 2020 02:41:09

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T08:34:17', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '1a83f11c-f857-422e-b159-a3aadde1b7d1'	System	16 Sep 2020 13:34:43
User entered 'None (0)'	System	16 Sep 2020 13:34:43

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T08:34:20', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '1a83f11c-f857-422e-b159-a3aadde1b7d1'	System	16 Sep 2020 13:34:43
User entered 'None (0)'	System	16 Sep 2020 13:34:43

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T08:34:23', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '1a83f11c-f857-422e-b159-a3aadde1b7d1'	System	16 Sep 2020 13:34:43
User entered 'None (0)'	System	16 Sep 2020 13:34:43

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T08:34:27', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '1a83f11c-f857-422e-b159-a3aadde1b7d1'	System	16 Sep 2020 13:34:43
User entered 'None (0)'	System	16 Sep 2020 13:34:43

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T08:34:29', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '1a83f11c-f857-422e-b159-a3aadde1b7d1'	System	16 Sep 2020 13:34:43
User entered 'None (0)'	System	16 Sep 2020 13:34:43

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T08:34:32', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '1a83f11c-f857-422e-b159-a3aadde1b7d1'	System	16 Sep 2020 13:34:43
User entered 'None (0)'	System	16 Sep 2020 13:34:43

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T08:34:35', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '1a83f11c-f857-422e-b159-a3aadde1b7d1'	System	16 Sep 2020 13:34:43
User entered 'No (N)'	System	16 Sep 2020 13:34:43

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T08:34:40', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '1a83f11c-f857-422e-b159-a3aadde1b7d1'	System	16 Sep 2020 13:34:43
User entered '16 Sep 2020 08:34'	System	16 Sep 2020 13:34:43

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '16 Sep 2020 08:22'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '16 Sep 2020 10:52'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T19:01:24', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '22c0fd22-9794-4f88-9520-9caefb0c5db2'	System	17 Sep 2020 00:01:50
User entered 'None (0)'	System	17 Sep 2020 00:01:50

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T19:01:27', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '22c0fd22-9794-4f88-9520-9caefb0c5db2'	System	17 Sep 2020 00:01:50
User entered 'None (0)'	System	17 Sep 2020 00:01:50

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T19:01:30', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '22c0fd22-9794-4f88-9520-9caefb0c5db2'	System	17 Sep 2020 00:01:50
User entered 'None (0)'	System	17 Sep 2020 00:01:50

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T19:01:32', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '22c0fd22-9794-4f88-9520-9caefb0c5db2'	System	17 Sep 2020 00:01:50
User entered 'None (0)'	System	17 Sep 2020 00:01:50

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T19:01:35', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '22c0fd22-9794-4f88-9520-9caefb0c5db2'	System	17 Sep 2020 00:01:50
User entered 'None (0)'	System	17 Sep 2020 00:01:50

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T19:01:37', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '22c0fd22-9794-4f88-9520-9caefb0c5db2'	System	17 Sep 2020 00:01:50
User entered 'None (0)'	System	17 Sep 2020 00:01:50

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T19:01:41', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '22c0fd22-9794-4f88-9520-9caefb0c5db2'	System	17 Sep 2020 00:01:50
User entered 'No (N)'	System	17 Sep 2020 00:01:50

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-16T19:01:47', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '22c0fd22-9794-4f88-9520-9caefb0c5db2'	System	17 Sep 2020 00:01:50
User entered '16 Sep 2020 19:01'	System	17 Sep 2020 00:01:50

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '16 Sep 2020 11:47'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 2'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-17T19:33:19', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'deb23ac2-1aae-4f92-afc0-ceed54219d44'	System	18 Sep 2020 00:33:49
User entered 'None (0)'	System	18 Sep 2020 00:33:49

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-17T19:33:23', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'deb23ac2-1aae-4f92-afc0-ceed54219d44'	System	18 Sep 2020 00:33:49
User entered 'None (0)'	System	18 Sep 2020 00:33:49

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-17T19:33:25', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'deb23ac2-1aae-4f92-afc0-ceed54219d44'	System	18 Sep 2020 00:33:49
User entered 'None (0)'	System	18 Sep 2020 00:33:49

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-17T19:33:27', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'deb23ac2-1aae-4f92-afc0-ceed54219d44'	System	18 Sep 2020 00:33:49
User entered 'None (0)'	System	18 Sep 2020 00:33:49

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-17T19:33:30', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'deb23ac2-1aae-4f92-afc0-ceed54219d44'	System	18 Sep 2020 00:33:49
User entered 'None (0)'	System	18 Sep 2020 00:33:49

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-17T19:33:33', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'deb23ac2-1aae-4f92-afc0-ceed54219d44'	System	18 Sep 2020 00:33:49
User entered 'None (0)'	System	18 Sep 2020 00:33:49

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-17T19:33:39', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'deb23ac2-1aae-4f92-afc0-ceed54219d44'	System	18 Sep 2020 00:33:49
User entered 'No (N)'	System	18 Sep 2020 00:33:49

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-17T19:33:47', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'deb23ac2-1aae-4f92-afc0-ceed54219d44'	System	18 Sep 2020 00:33:49
User entered '17 Sep 2020 19:33'	System	18 Sep 2020 00:33:49

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 3'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T05:17:44', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '9c884264-bf0e-4c5b-b49d-84ce846efd84'	System	19 Sep 2020 10:18:15
User entered 'None (0)'	System	19 Sep 2020 10:18:15

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T05:17:47', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '9c884264-bf0e-4c5b-b49d-84ce846efd84'	System	19 Sep 2020 10:18:15
User entered 'None (0)'	System	19 Sep 2020 10:18:15

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T05:17:50', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '9c884264-bf0e-4c5b-b49d-84ce846efd84'	System	19 Sep 2020 10:18:15
User entered 'None (0)'	System	19 Sep 2020 10:18:15

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T05:17:53', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '9c884264-bf0e-4c5b-b49d-84ce846efd84'	System	19 Sep 2020 10:18:15
User entered 'None (0)'	System	19 Sep 2020 10:18:15

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T05:18:01', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '9c884264-bf0e-4c5b-b49d-84ce846efd84'	System	19 Sep 2020 10:18:15
User entered 'None (0)'	System	19 Sep 2020 10:18:15

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T05:18:04', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '9c884264-bf0e-4c5b-b49d-84ce846efd84'	System	19 Sep 2020 10:18:15
User entered 'None (0)'	System	19 Sep 2020 10:18:15

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T05:18:08', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '9c884264-bf0e-4c5b-b49d-84ce846efd84'	System	19 Sep 2020 10:18:15
User entered 'No (N)'	System	19 Sep 2020 10:18:15

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T05:18:12', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '9c884264-bf0e-4c5b-b49d-84ce846efd84'	System	19 Sep 2020 10:18:15
User entered '19 Sep 2020 05:18'	System	19 Sep 2020 10:18:15

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 4'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T20:22:14', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c629e181-b553-4ca8-8e24-45d590198b00'	System	20 Sep 2020 01:22:37
User entered 'None (0)'	System	20 Sep 2020 01:22:37

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T20:22:16', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c629e181-b553-4ca8-8e24-45d590198b00'	System	20 Sep 2020 01:22:37
User entered 'None (0)'	System	20 Sep 2020 01:22:37

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T20:22:18', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c629e181-b553-4ca8-8e24-45d590198b00'	System	20 Sep 2020 01:22:37
User entered 'None (0)'	System	20 Sep 2020 01:22:37

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T20:22:21', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c629e181-b553-4ca8-8e24-45d590198b00'	System	20 Sep 2020 01:22:37
User entered 'None (0)'	System	20 Sep 2020 01:22:37

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T20:22:24', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c629e181-b553-4ca8-8e24-45d590198b00'	System	20 Sep 2020 01:22:37
User entered 'None (0)'	System	20 Sep 2020 01:22:37

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T20:22:26', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c629e181-b553-4ca8-8e24-45d590198b00'	System	20 Sep 2020 01:22:37
User entered 'None (0)'	System	20 Sep 2020 01:22:37

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T20:22:29', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c629e181-b553-4ca8-8e24-45d590198b00'	System	20 Sep 2020 01:22:37
User entered 'No (N)'	System	20 Sep 2020 01:22:37

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-19T20:22:35', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c629e181-b553-4ca8-8e24-45d590198b00'	System	20 Sep 2020 01:22:37
User entered '19 Sep 2020 20:22'	System	20 Sep 2020 01:22:37

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 5'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-20T20:03:36', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'afd05f0a-ba4c-4926-8351-fae8b61acb3b'	System	21 Sep 2020 01:03:53
User entered 'None (0)'	System	21 Sep 2020 01:03:53

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-20T20:03:38', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'afd05f0a-ba4c-4926-8351-fae8b61acb3b'	System	21 Sep 2020 01:03:53
User entered 'None (0)'	System	21 Sep 2020 01:03:53

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-20T20:03:40', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'afd05f0a-ba4c-4926-8351-fae8b61acb3b'	System	21 Sep 2020 01:03:53
User entered 'None (0)'	System	21 Sep 2020 01:03:53

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-20T20:03:42', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'afd05f0a-ba4c-4926-8351-fae8b61acb3b'	System	21 Sep 2020 01:03:53
User entered 'None (0)'	System	21 Sep 2020 01:03:53

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-20T20:03:44', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'afd05f0a-ba4c-4926-8351-fae8b61acb3b'	System	21 Sep 2020 01:03:53
User entered 'None (0)'	System	21 Sep 2020 01:03:53

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-20T20:03:47', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'afd05f0a-ba4c-4926-8351-fae8b61acb3b'	System	21 Sep 2020 01:03:53
User entered 'None (0)'	System	21 Sep 2020 01:03:53

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-20T20:03:50', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'afd05f0a-ba4c-4926-8351-fae8b61acb3b'	System	21 Sep 2020 01:03:53
User entered 'No (N)'	System	21 Sep 2020 01:03:53

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-20T20:03:52', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'afd05f0a-ba4c-4926-8351-fae8b61acb3b'	System	21 Sep 2020 01:03:53
User entered '20 Sep 2020 20:03'	System	21 Sep 2020 01:03:53

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 6'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-21T21:59:01', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '3071e4cd-99b5-48b8-aabe-3a4a4ce1a75e'	System	22 Sep 2020 02:59:23
User entered 'None (0)'	System	22 Sep 2020 02:59:23

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-21T21:59:03', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '3071e4cd-99b5-48b8-aabe-3a4a4ce1a75e'	System	22 Sep 2020 02:59:23
User entered 'None (0)'	System	22 Sep 2020 02:59:23

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-21T21:59:05', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '3071e4cd-99b5-48b8-aabe-3a4a4ce1a75e'	System	22 Sep 2020 02:59:23
User entered 'None (0)'	System	22 Sep 2020 02:59:23

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-21T21:59:07', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '3071e4cd-99b5-48b8-aabe-3a4a4ce1a75e'	System	22 Sep 2020 02:59:23
User entered 'None (0)'	System	22 Sep 2020 02:59:23

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-21T21:59:10', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '3071e4cd-99b5-48b8-aabe-3a4a4ce1a75e'	System	22 Sep 2020 02:59:23
User entered 'None (0)'	System	22 Sep 2020 02:59:23

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-21T21:59:12', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '3071e4cd-99b5-48b8-aabe-3a4a4ce1a75e'	System	22 Sep 2020 02:59:23
User entered 'None (0)'	System	22 Sep 2020 02:59:23

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-21T21:59:16', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '3071e4cd-99b5-48b8-aabe-3a4a4ce1a75e'	System	22 Sep 2020 02:59:23
User entered 'No (N)'	System	22 Sep 2020 02:59:23

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-21T21:59:19', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '3071e4cd-99b5-48b8-aabe-3a4a4ce1a75e'	System	22 Sep 2020 02:59:23
User entered '21 Sep 2020 21:59'	System	22 Sep 2020 02:59:23

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	16 Sep 2020 13:04:16
User entered 'Day 7'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-22T21:41:08', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e12de42c-003f-4409-8577-4081d6f6588e'	System	23 Sep 2020 02:41:33
User entered 'None (0)'	System	23 Sep 2020 02:41:33

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-22T21:41:10', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e12de42c-003f-4409-8577-4081d6f6588e'	System	23 Sep 2020 02:41:33
User entered 'None (0)'	System	23 Sep 2020 02:41:33

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-22T21:41:14', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e12de42c-003f-4409-8577-4081d6f6588e'	System	23 Sep 2020 02:41:33
User entered 'None (0)'	System	23 Sep 2020 02:41:33

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-22T21:41:17', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e12de42c-003f-4409-8577-4081d6f6588e'	System	23 Sep 2020 02:41:33
User entered 'None (0)'	System	23 Sep 2020 02:41:33

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-22T21:41:19', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e12de42c-003f-4409-8577-4081d6f6588e'	System	23 Sep 2020 02:41:33
User entered 'None (0)'	System	23 Sep 2020 02:41:33

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-22T21:41:22', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e12de42c-003f-4409-8577-4081d6f6588e'	System	23 Sep 2020 02:41:33
User entered 'None (0)'	System	23 Sep 2020 02:41:33

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-22T21:41:26', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e12de42c-003f-4409-8577-4081d6f6588e'	System	23 Sep 2020 02:41:33
User entered 'No (N)'	System	23 Sep 2020 02:41:33

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-09-22T21:41:29', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e12de42c-003f-4409-8577-4081d6f6588e'	System	23 Sep 2020 02:41:33
User entered '22 Sep 2020 21:41'	System	23 Sep 2020 02:41:33

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 13:04:16

US3782028

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 13:04:16

US3782028

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:53:12

US3782028

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:53:12

US3782028

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:53:12

US3782028

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:53:12

US3782028

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:53:16

US3782028

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'I'	System	23 Sep 2020 16:53:16

US3782028

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:39:57

US3782028

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:39:57

US3782028

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:39:57

US3782028

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:39:57

US3782028

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 13:40:04

US3782028

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'I'	System	30 Sep 2020 13:40:04

US3782028

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:12:03

US3782028

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:12:03

US3782028

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:12:03

US3782028

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:12:03

US3782028

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:12:08

US3782028

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'I'	System	07 Oct 2020 14:12:08

US3782028

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	14 Oct 2020 12:34:11

US3782028

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '14 Oct 2020'	(b) (4) Carlton Griffin (b) (4)	14 Oct 2020 12:34:11

US3782028

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

[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 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Clinic (Clinic)'	Carlton Griffin (b) (4)	14 Oct 2020 12:34:11

US3782028

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'VISIT3'	System	14 Oct 2020 12:34:11

US3782028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	14 Oct 2020 12:34:37

US3782028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '14 Oct 2020'	(b) (4) Carlton Griffin (b) (4)	14 Oct 2020 12:34:37

US3782028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '07:23'	(b) (4) Carlton Griffin (b) (4)	14 Oct 2020 12:34:37

US3782028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered '14 Oct 2020 07:23'	System	14 Oct 2020 12:34:37

US3782028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '98.2' F	Carlton Griffin (b) (4)	14 Oct 2020 12:34:37

US3782028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Oral (Oral)'	Carlton Griffin (b) (4)	14 Oct 2020 12:34:37

US3782028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) Carlton Griffin (b) (4)	14 Oct 2020 12:34:37

US3782028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '71'	Carlton Griffin (b) (4)	14 Oct 2020 12:34:37

US3782028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'bpm'	System	14 Oct 2020 12:34:37

US3782028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16'	Carlton Griffin (b) (4)	14 Oct 2020 12:34:37

US3782028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'breaths/min'	System	14 Oct 2020 12:34:37

US3782028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '139'	Carlton Griffin (b) (4)	14 Oct 2020 12:34:37

US3782028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'mmHg'	System	14 Oct 2020 12:34:37

US3782028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:33:30
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Carlton Griffin (b) (4) (b) (4)	14 Oct 2020 12:34:45
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		14 Oct 2020 12:34:37
User entered '59'	Carlton Griffin (b) (4) (b) (4)	14 Oct 2020 12:34:37

US3782028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'mmHg'	System	14 Oct 2020 12:34:37

US3782028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47

US3782028

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47

US3782028

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	14 Oct 2020 12:34:53

US3782028

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '14 Oct 2020'	(b) (4) Carlton Griffin (b) (4)	14 Oct 2020 12:34:53

US3782028

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	14 Oct 2020 12:35:04

US3782028

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '14 Oct 2020'	(b) (4) Carlton Griffin (b) (4)	14 Oct 2020 12:35:04

US3782028

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '07:19'	(b) (4) Carlton Griffin (b) (4)	14 Oct 2020 12:35:04

US3782028

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered '14 Oct 2020 07:19'	System	14 Oct 2020 12:35:04

US3782028

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	14 Oct 2020 12:35:30

US3782028

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered '1'	System	14 Oct 2020 12:35:30

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 64'	System	19 Aug 2020 13:32:21

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-10-21T07:55:52', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c863b3eb-2c96-454e-8460-b75815da1d4a'	System	21 Oct 2020 12:56:11
User entered 'No (N)'	System	21 Oct 2020 12:56:11

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-10-21T07:55:58', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c863b3eb-2c96-454e-8460-b75815da1d4a'	System	21 Oct 2020 12:56:11
User entered 'No (N)'	System	21 Oct 2020 12:56:11

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-10-21T07:56:07', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c863b3eb-2c96-454e-8460-b75815da1d4a'	System	21 Oct 2020 12:56:11
User entered '21 Oct 2020 07:56:07'	System	21 Oct 2020 12:56:11

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 13:32:21

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 71'	System	19 Aug 2020 13:32:21

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-10-28T14:51:17', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '0b3663af-d169-4c61-8ade-4ae104e1da71'	System	28 Oct 2020 19:51:37
User entered 'No (N)'	System	28 Oct 2020 19:51:37

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-10-28T14:51:24', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '0b3663af-d169-4c61-8ade-4ae104e1da71'	System	28 Oct 2020 19:51:37
User entered 'No (N)'	System	28 Oct 2020 19:51:37

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-10-28T14:51:32', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '0b3663af-d169-4c61-8ade-4ae104e1da71'	System	28 Oct 2020 19:51:37
User entered '28 Oct 2020 14:51:32'	System	28 Oct 2020 19:51:37

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 13:32:21

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 78'	System	19 Aug 2020 13:32:21

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-11-04T08:00:40', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e5947bad-8b9b-4e6f-a57e-17ac90d06428'	System	04 Nov 2020 14:00:52
User entered 'No (N)'	System	04 Nov 2020 14:00:52

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-11-04T08:00:44', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e5947bad-8b9b-4e6f-a57e-17ac90d06428'	System	04 Nov 2020 14:00:52
User entered 'No (N)'	System	04 Nov 2020 14:00:52

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-11-04T08:00:50', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e5947bad-8b9b-4e6f-a57e-17ac90d06428'	System	04 Nov 2020 14:00:52
User entered '04 Nov 2020 08:00:50'	System	04 Nov 2020 14:00:52

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 13:32:21

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered 'Day 92'	System	19 Aug 2020 13:32:21

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-11-18T07:59:28', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c6404f44-cb9e-4977-85db-44e6bbad70f5'	System	18 Nov 2020 13:59:45
User entered 'No (N)'	System	18 Nov 2020 13:59:45

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-11-18T07:59:35', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c6404f44-cb9e-4977-85db-44e6bbad70f5'	System	18 Nov 2020 13:59:45
User entered 'No (N)'	System	18 Nov 2020 13:59:45

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-11-18T07:59:42', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c6404f44-cb9e-4977-85db-44e6bbad70f5' User entered '18 Nov 2020 07:59:42'	System	18 Nov 2020 13:59:45
	System	18 Nov 2020 13:59:45

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 13:32:21

US3782028

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:45:32
Data entry locked.	System	19 Aug 2020 13:32:21
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 13:32:21

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2020-11-23T07:53:06', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7122c448-3f2b-46a6-b5ef-1119fd9a1b21'	System	23 Nov 2020 13:53:15
User entered 'No (N)'	System	23 Nov 2020 13:53:15

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2020-11-23T07:53:09', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7122c448-3f2b-46a6-b5ef-1119fd9a1b21'	System	23 Nov 2020 13:53:15
User entered 'No (N)'	System	23 Nov 2020 13:53:15

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-11-23T07:53:12', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7122c448-3f2b-46a6-b5ef-1119fd9a1b21'	System	23 Nov 2020 13:53:15
User entered '23 Nov 2020 07:53:12'	System	23 Nov 2020 13:53:15

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2020-11-27T05:43:04', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '0758152c-91f6-470b-a88a-1cfd6cc5ed4b'	System	27 Nov 2020 10:43:16
User entered 'No (N)'	System	27 Nov 2020 10:43:16

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2020-11-27T05:43:07', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '0758152c-91f6-470b-a88a-1cfd6cc5ed4b'	System	27 Nov 2020 10:43:16
User entered 'No (N)'	System	27 Nov 2020 10:43:16

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-11-27T05:43:12', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '0758152c-91f6-470b-a88a-1cfd6cc5ed4b'	System	27 Nov 2020 10:43:16
User entered '27 Nov 2020 05:43:12'	System	27 Nov 2020 10:43:16

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2020-12-04T06:04:25', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7462df64-5d66-4f7d-a44b-15ed815878af'	System	04 Dec 2020 12:04:37
User entered 'No (N)'	System	04 Dec 2020 12:04:37

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2020-12-04T06:04:28', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7462df64-5d66-4f7d-a44b-15ed815878af'	System	04 Dec 2020 12:04:37
User entered 'No (N)'	System	04 Dec 2020 12:04:37

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-12-04T06:04:34', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7462df64-5d66-4f7d-a44b-15ed815878af' User entered '04 Dec 2020 06:04:34'	System	04 Dec 2020 12:04:37
	System	04 Dec 2020 12:04:37

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2020-12-11T09:36:55', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'cc1cfa63-01b6-4151-ae7c-a8a0bb54e6cd'	System	11 Dec 2020 15:37:03
User entered 'No (N)'	System	11 Dec 2020 15:37:03

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2020-12-11T09:36:58', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'cc1cfa63-01b6-4151-ae7c-a8a0bb54e6cd'	System	11 Dec 2020 15:37:03
User entered 'No (N)'	System	11 Dec 2020 15:37:03

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-12-11T09:37:01', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'cc1cfa63-01b6-4151-ae7c-a8a0bb54e6cd' User entered '11 Dec 2020 09:37:01'	System	11 Dec 2020 15:37:03

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2020-12-18T18:51:21', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'aa3722d8-b70c-4834-843e-0445b748353c'	System	19 Dec 2020 00:52:07
User entered 'Yes (Y)'	System	19 Dec 2020 00:52:07

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2020-12-18T18:51:25', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'aa3722d8-b70c-4834-843e-0445b748353c'	System	19 Dec 2020 00:52:07
User entered 'No (N)'	System	19 Dec 2020 00:52:07

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2020-12-18T18:51:31', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'aa3722d8-b70c-4834-843e-0445b748353c'	System	19 Dec 2020 00:52:07
User entered 'No (N)'	System	19 Dec 2020 00:52:07

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2020-12-18T18:51:43', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'aa3722d8-b70c-4834-843e-0445b748353c'	System	19 Dec 2020 00:52:07
User entered 'Yes (Y)'	System	19 Dec 2020 00:52:07

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Please 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 (dc16db1e18ba9225)', Time: '2020-12-18T18:51:52', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'aa3722d8-b70c-4834-843e-0445b748353c'	System	19 Dec 2020 00:52:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Dec 2020 00:52:07

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-12-18T18:51:58', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'aa3722d8-b70c-4834-843e-0445b748353c'	System	19 Dec 2020 00:52:07
User entered '18 Dec 2020 18:51:58'	System	19 Dec 2020 00:52:07

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2020-12-25T06:11:34', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '1d515a63-f5bd-4afc-962f-2203d6797720'	System	25 Dec 2020 12:11:51
User entered 'No (N)'	System	25 Dec 2020 12:11:51

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2020-12-25T06:11:39', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '1d515a63-f5bd-4afc-962f-2203d6797720'	System	25 Dec 2020 12:11:51
User entered 'No (N)'	System	25 Dec 2020 12:11:51

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2020-12-25T06:11:46', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '1d515a63-f5bd-4afc-962f-2203d6797720'	System	25 Dec 2020 12:11:51
User entered '25 Dec 2020 06:11:46'	System	25 Dec 2020 12:11:51

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-01-01T13:26:15', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'ca251ee4-4ebf-496d-a6b6-8959aa3e61c8'	System	01 Jan 2021 19:26:25
User entered 'No (N)'	System	01 Jan 2021 19:26:25

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2021-01-01T13:26:18', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'ca251ee4-4ebf-496d-a6b6-8959aa3e61c8'	System	01 Jan 2021 19:26:25
User entered 'No (N)'	System	01 Jan 2021 19:26:25

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-01-01T13:26:21', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'ca251ee4-4ebf-496d-a6b6-8959aa3e61c8'	System	01 Jan 2021 19:26:25
User entered '01 Jan 2021 13:26:21'	System	01 Jan 2021 19:26:25

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-01-08T09:52:17', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a2ef387d-2230-4a89-96ff-aac4d9c00ff0'	System	08 Jan 2021 15:52:28
User entered 'No (N)'	System	08 Jan 2021 15:52:28

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2021-01-08T09:52:20', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a2ef387d-2230-4a89-96ff-aac4d9c00ff0'	System	08 Jan 2021 15:52:28
User entered 'No (N)'	System	08 Jan 2021 15:52:28

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-01-08T09:52:26', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'a2ef387d-2230-4a89-96ff-aac4d9c00ff0'	System	08 Jan 2021 15:52:28
User entered '08 Jan 2021 09:52:26'	System	08 Jan 2021 15:52:28

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-01-15T08:50:25', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'fd4b3c50-4b85-4855-b646-e9cc437ed723'	System	15 Jan 2021 14:50:39
User entered 'No (N)'	System	15 Jan 2021 14:50:39

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2021-01-15T08:50:28', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'fd4b3c50-4b85-4855-b646-e9cc437ed723'	System	15 Jan 2021 14:50:39
User entered 'No (N)'	System	15 Jan 2021 14:50:39

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-01-15T08:50:34', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'fd4b3c50-4b85-4855-b646-e9cc437ed723'	System	15 Jan 2021 14:50:39
User entered '15 Jan 2021 08:50:34'	System	15 Jan 2021 14:50:39

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-01-22T07:21:57', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '367f3539-e8e2-4e82-995e-f37c9db9756a'	System	22 Jan 2021 13:22:09
User entered 'No (N)'	System	22 Jan 2021 13:22:09

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2021-01-22T07:22:03', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '367f3539-e8e2-4e82-995e-f37c9db9756a'	System	22 Jan 2021 13:22:09
User entered 'No (N)'	System	22 Jan 2021 13:22:09

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-01-22T07:22:06', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '367f3539-e8e2-4e82-995e-f37c9db9756a' User entered '22 Jan 2021 07:22:06'	System	22 Jan 2021 13:22:09

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-01-31T21:00:40', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'cc6f21ae-c3e8-4720-a518-b42239677b32'	System	01 Feb 2021 03:01:14
User entered 'No (N)'	System	01 Feb 2021 03:01:14

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2021-01-31T21:00:43', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'cc6f21ae-c3e8-4720-a518-b42239677b32'	System	01 Feb 2021 03:01:14
User entered 'No (N)'	System	01 Feb 2021 03:01:14

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-01-31T21:00:49', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'cc6f21ae-c3e8-4720-a518-b42239677b32'	System	01 Feb 2021 03:01:14
User entered '31 Jan 2021 21:00:49'	System	01 Feb 2021 03:01:14

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-02-05T05:42:10', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'cb288037-8fb1-47ad-a377-fdd09799b377'	System	05 Feb 2021 11:42:18
User entered 'No (N)'	System	05 Feb 2021 11:42:18

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2021-02-05T05:42:13', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'cb288037-8fb1-47ad-a377-fdd09799b377'	System	05 Feb 2021 11:42:18
User entered 'No (N)'	System	05 Feb 2021 11:42:18

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-02-05T05:42:16', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'cb288037-8fb1-47ad-a377-fdd09799b377'	System	05 Feb 2021 11:42:18
User entered '05 Feb 2021 05:42:16'	System	05 Feb 2021 11:42:18

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-02-12T14:00:49', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '6f6cfc74-18dd-4457-98e4-f6ecbefa5e39'	System	12 Feb 2021 20:01:28
User entered 'No (N)'	System	12 Feb 2021 20:01:28

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2021-02-12T14:00:53', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '6f6cfc74-18dd-4457-98e4-f6ecbfa5e39'	System	12 Feb 2021 20:01:28
User entered 'No (N)'	System	12 Feb 2021 20:01:28

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-02-12T14:00:56', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '6f6cfc74-18dd-4457-98e4-f6ecbfa5e39'	System	12 Feb 2021 20:01:28
User entered '12 Feb 2021 14:00:56'	System	12 Feb 2021 20:01:28

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-02-19T08:06:22', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '8603882a-e6ce-4903-aef0-5e23f84b9dcb'	System	19 Feb 2021 14:06:29
User entered 'No (N)'	System	19 Feb 2021 14:06:29

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2021-02-19T08:06:24', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '8603882a-e6ce-4903-aef0-5e23f84b9dcb'	System	19 Feb 2021 14:06:29
User entered 'No (N)'	System	19 Feb 2021 14:06:29

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-02-19T08:06:27', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '8603882a-e6ce-4903-aef0-5e23f84b9dcb' User entered '19 Feb 2021 08:06:27'	System	19 Feb 2021 14:06:29
	System	19 Feb 2021 14:06:29

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-02-26T08:00:12-06:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '1f734981-df44-4a1a-9d95-5265e5c0fe19'	System	26 Feb 2021 14:00:55
User entered 'Yes (Y)'	System	26 Feb 2021 14:00:55

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2021-02-26T08:00:17-06:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '1f734981-df44-4a1a-9d95-5265e5c0fe19'	System	26 Feb 2021 14:00:55
User entered 'No (N)'	System	26 Feb 2021 14:00:55

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-02-26T08:00:22-06:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '1f734981-df44-4a1a-9d95-5265e5c0fe19'	System	26 Feb 2021 14:00:55
User entered 'No (N)'	System	26 Feb 2021 14:00:55

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-02-26T08:00:31-06:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '1f734981-df44-4a1a-9d95-5265e5c0fe19'	System	26 Feb 2021 14:00:55
User entered 'Yes (Y)'	System	26 Feb 2021 14:00:55

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Please 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 (dc16db1e18ba9225)', Time: '2021-02-26T08:00:38-06:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '1f734981-df44-4a1a-9d95-5265e5c0fe19'	System	26 Feb 2021 14:00:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Feb 2021 14:00:55

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-02-26T08:00:43-06:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '1f734981-df44-4a1a-9d95-5265e5c0fe19'	System	26 Feb 2021 14:00:55
User entered '26 Feb 2021 08:00:43'	System	26 Feb 2021 14:00:55

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-03-05T05:16:34-06:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'fafc2d4f-179a-4eab-8e97-10ce1d25f11e'	System	05 Mar 2021 11:16:46
User entered 'No (N)'	System	05 Mar 2021 11:16:46

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2021-03-05T05:16:37-06:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'fafc2d4f-179a-4eab-8e97-10ce1d25f11e'	System	05 Mar 2021 11:16:46
User entered 'No (N)'	System	05 Mar 2021 11:16:46

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-03-05T05:16:42-06:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'fafc2d4f-179a-4eab-8e97-10ce1d25f11e' User entered '05 Mar 2021 05:16:42'	System	05 Mar 2021 11:16:46
	System	05 Mar 2021 11:16:46

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-03-12T04:26:58-06:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e0f11e47-c05e-4777-b77a-75805a1724c3'	System	12 Mar 2021 10:27:08
User entered 'No (N)'	System	12 Mar 2021 10:27:08

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2021-03-12T04:27:00-06:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e0f11e47-c05e-4777-b77a-75805a1724c3'	System	12 Mar 2021 10:27:08
User entered 'No (N)'	System	12 Mar 2021 10:27:08

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-03-12T04:27:06-06:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'e0f11e47-c05e-4777-b77a-75805a1724c3'	System	12 Mar 2021 10:27:08
User entered '12 Mar 2021 04:27:06'	System	12 Mar 2021 10:27:08

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-03-19T08:07:12-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '71780941-668c-415c-b030-6318db68861f' User entered 'No (N)'	System	19 Mar 2021 13:07:23
	System	19 Mar 2021 13:07:23

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2021-03-19T08:07:16-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '71780941-668c-415c-b030-6318db68861f'	System	19 Mar 2021 13:07:23
User entered 'No (N)'	System	19 Mar 2021 13:07:23

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-03-19T08:07:19-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '71780941-668c-415c-b030-6318db68861f' User entered '19 Mar 2021 08:07:19'	System	19 Mar 2021 13:07:23
	System	19 Mar 2021 13:07:23

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-03-26T04:27:28-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '5ebc2646-4ca5-4e55-ba9b-f15d1df742ba'	System	26 Mar 2021 09:27:40
User entered 'No (N)'	System	26 Mar 2021 09:27:40

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2021-03-26T04:27:33-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '5ebc2646-4ca5-4e55-ba9b-f15d1df742ba'	System	26 Mar 2021 09:27:40
User entered 'No (N)'	System	26 Mar 2021 09:27:40

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-03-26T04:27:37-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '5ebc2646-4ca5-4e55-ba9b-f15d1df742ba' User entered '26 Mar 2021 04:27:37'	System	26 Mar 2021 09:27:40
	System	26 Mar 2021 09:27:40

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-04-02T05:01:20-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '27b0d4e1-b7c2-4a39-8579-4bf7f963e674'	System	02 Apr 2021 10:01:29
User entered 'No (N)'	System	02 Apr 2021 10:01:29

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2021-04-02T05:01:23-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '27b0d4e1-b7c2-4a39-8579-4bf7f963e674'	System	02 Apr 2021 10:01:29
User entered 'No (N)'	System	02 Apr 2021 10:01:29

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-04-02T05:01:26-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '27b0d4e1-b7c2-4a39-8579-4bf7f963e674'	System	02 Apr 2021 10:01:29
User entered '02 Apr 2021 05:01:26'	System	02 Apr 2021 10:01:29

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-04-09T04:26:06-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f06a11a4-04eb-4382-9bf5-0396cc3fd7c6'	System	09 Apr 2021 09:26:48
User entered 'No (N)'	System	09 Apr 2021 09:26:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2021-04-09T04:26:12-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f06a11a4-04eb-4382-9bf5-0396cc3fd7c6'	System	09 Apr 2021 09:26:48
User entered 'No (N)'	System	09 Apr 2021 09:26:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-04-09T04:26:15-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'f06a11a4-04eb-4382-9bf5-0396cc3fd7c6'	System	09 Apr 2021 09:26:48
User entered '09 Apr 2021 04:26:15'	System	09 Apr 2021 09:26:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-04-19T05:47:45-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7909083a-0b28-4ad2-9f6b-5253fde24f5f'	System	19 Apr 2021 10:47:52
User entered 'No (N)'	System	19 Apr 2021 10:47:52

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2021-04-19T05:47:47-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7909083a-0b28-4ad2-9f6b-5253fde24f5f' User entered 'No (N)'	System	19 Apr 2021 10:47:52

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-04-19T05:47:49-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '7909083a-0b28-4ad2-9f6b-5253fde24f5f'	System	19 Apr 2021 10:47:52
User entered '19 Apr 2021 05:47:49'	System	19 Apr 2021 10:47:52

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-04-23T05:47:52-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '8b68217d-ea61-4a42-b1a9-f34191f81de8'	System	23 Apr 2021 10:48:00
User entered 'No (N)'	System	23 Apr 2021 10:48:00

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2021-04-23T05:47:54-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '8b68217d-ea61-4a42-b1a9-f34191f81de8'	System	23 Apr 2021 10:48:00
User entered 'No (N)'	System	23 Apr 2021 10:48:00

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-04-23T05:47:58-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '8b68217d-ea61-4a42-b1a9-f34191f81de8'	System	23 Apr 2021 10:48:00
User entered '23 Apr 2021 05:47:58'	System	23 Apr 2021 10:48:00

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[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 (dc16db1e18ba9225)', Time: '2021-04-30T05:06:53-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '27800ebd-d6ef-461d-9aff-93e0a0449a86'	System	30 Apr 2021 10:07:02
User entered 'No (N)'	System	30 Apr 2021 10:07:02

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

Have you been exposed to someone with 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 (dc16db1e18ba9225)', Time: '2021-04-30T05:06:55-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '27800ebd-d6ef-461d-9aff-93e0a0449a86'	System	30 Apr 2021 10:07:02
User entered 'No (N)'	System	30 Apr 2021 10:07:02

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-04-30T05:06:58-05:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: '27800ebd-d6ef-461d-9aff-93e0a0449a86'	System	30 Apr 2021 10:07:02
User entered '30 Apr 2021 05:06:58'	System	30 Apr 2021 10:07:02

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 08:52:48

US3782028

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:52:48
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 08:52:48

US3782028

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:48:20

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:58:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-03-05T05:16:48-06:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c8fc42f5-020c-4af7-938a-218e2dc26656'	System	05 Mar 2021 11:16:53
User entered 'No (N)'	System	05 Mar 2021 11:16:53

US3782028

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:48:20

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:58:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (dc16db1e18ba9225)', Time: '2021-03-05T05:16:51-06:00', User OID: 'PatientReportedOutcome (US3782028)', ODM File OID: 'c8fc42f5-020c-4af7-938a-218e2dc26656'	System	05 Mar 2021 11:16:53
User entered '05 Mar 2021 05:16:51'	System	05 Mar 2021 11:16:53

US3782028

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	11 Nov 2020 15:58:56

US3782028

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '11 Nov 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	11 Nov 2020 15:58:56

US3782028

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	11 Nov 2020 15:58:56

US3782028

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	Carlton Griffin (b) (4)	11 Nov 2020 15:58:56

US3782028

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	11 Nov 2020 15:59:05

US3782028

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:07:47
User entered 'I'	System	11 Nov 2020 15:59:05

US3782028

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:57:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	15 Dec 2020 15:01:09
	(b) (4)	

US3782028

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:57:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered '15 Dec 2020'	Carlton Griffin (b) (4)	15 Dec 2020 15:01:09
	(b) (4)	

US3782028

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:57:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4)	15 Dec 2020 15:01:09
	(b) (4)	

US3782028

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:57:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	15 Dec 2020 15:01:09
	(b) (4)	

US3782028

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:57:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	15 Dec 2020 15:01:16
	(b) (4)	

US3782028

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:57:36
User entered 'I'	System	15 Dec 2020 15:01:16

US3782028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:57:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 17:22:59

US3782028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:57:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered '14 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 17:22:59

US3782028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:57:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Jan 2021 17:22:59

US3782028

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:57:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Jan 2021 17:22:59

US3782028

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:57:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 17:23:06

US3782028

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:57:36
User entered 'I'	System	14 Jan 2021 17:23:06

US3782028

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:57:36
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:25:16
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	12 Feb 2021 19:58:45
	(b) (4)	

US3782028

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:57:36
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:25:16
	(b) (4)	
User entered '12 Feb 2021'	Carlton Griffin (b) (4)	12 Feb 2021 19:58:45
	(b) (4)	

US3782028

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:57:36
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:25:16
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4)	12 Feb 2021 19:58:45
	(b) (4)	

US3782028

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:57:36
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:25:16
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	12 Feb 2021 19:58:45
	(b) (4)	

US3782028

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:57:36
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:25:16
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	12 Feb 2021 19:58:28
	(b) (4)	

US3782028

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:57:36
User entered 'I'	System	12 Feb 2021 19:58:28

US3782028

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	18 Mar 2021 13:16:38

US3782028

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered '18 Mar 2021'	(b) (4) Carlton Griffin (b) (4)	18 Mar 2021 13:16:38
	(b) (4)	

US3782028

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered 'Clinic (Clinic)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:16:38

US3782028

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered 'VISIT4'	System	18 Mar 2021 13:16:38

US3782028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	30 Mar 2021 13:54:27

US3782028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered empty.	(b) (4) Carlton Griffin (b) (4)	30 Mar 2021 13:54:27

US3782028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered empty.	(b) (4) Carlton Griffin (b) (4)	30 Mar 2021 13:54:27

US3782028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered empty.	System	30 Mar 2021 13:54:27

US3782028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered empty.	(b) (4) Carlton Griffin (b) (4)	30 Mar 2021 13:54:27

US3782028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered empty.	(b) (4) Carlton Griffin (b) (4)	30 Mar 2021 13:54:27

US3782028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered empty.	(b) (4) Carlton Griffin (b) (4)	30 Mar 2021 13:54:27

US3782028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered empty.	(b) (4) Carlton Griffin (b) (4)	30 Mar 2021 13:54:27

US3782028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered empty.	System	30 Mar 2021 13:54:27

US3782028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered empty.	(b) (4) Carlton Griffin (b) (4)	30 Mar 2021 13:54:27

US3782028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered empty.	System	30 Mar 2021 13:54:27

US3782028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered empty.	(b) (4) Carlton Griffin (b) (4)	30 Mar 2021 13:54:27

US3782028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered empty.	System	30 Mar 2021 13:54:27

US3782028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered empty.	(b) (4) Carlton Griffin (b) (4)	30 Mar 2021 13:54:27

US3782028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered empty.	System	30 Mar 2021 13:54:27

US3782028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 08:11:19

US3782028

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 08:11:19

US3782028

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	18 Mar 2021 13:16:47

US3782028

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered '18 Mar 2021'	(b) (4) Carlton Griffin (b) (4)	18 Mar 2021 13:16:47
	(b) (4)	

US3782028

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	18 Mar 2021 13:27:00

US3782028

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered '18 Mar 2021'	(b) (4) Carlton Griffin (b) (4)	18 Mar 2021 13:27:00
	(b) (4)	

US3782028

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered '08:20'	(b) (4) Carlton Griffin (b) (4)	18 Mar 2021 13:27:00

US3782028

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered '18 Mar 2021 08:20'	System	18 Mar 2021 13:27:00

US3782028

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	18 Mar 2021 13:16:54

US3782028

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:11:19
User entered 'I'	System	18 Mar 2021 13:16:54

US3782028

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

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	04 Jan 2021 16:19:05

US3782028

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

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '4 Jan 2021'	(b) (4) Carlton Griffin (b) (4)	04 Jan 2021 16:19:05

US3782028

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

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

[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 12:38:45
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Clinic (Clinic)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	04 Jan 2021 16:19:05

US3782028

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

Form: Visit Date

Generated On: 10 Jun 2021 09:48:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User entered 'UNBLND_DECIDE'	System	04 Jan 2021 16:19:05

US3782028

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:20

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '4 Jan 2021'	(b) (4) Carlton Griffin (b) (4) (b) (4)	04 Jan 2021 16:19:17

US3782028

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:20

[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 12:38:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:52:06

US3782028

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:20

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	04 Jan 2021 16:19:17

US3782028

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:20

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:52:06

US3782028

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:20

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '4 Jan 2021'	(b) (4) Carlton Griffin (b) (4)	04 Jan 2021 16:19:17

US3782028

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:20

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Carlton Griffin (b) (4)	04 Jan 2021 16:19:17

US3782028

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:20

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 12:02:56
User entered 'mRNA-1273 (mRNA-1273)'	Carlton Griffin (b) (4) (b) (4)	04 Jan 2021 16:19:17

US3782028

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:20

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 12:02:56
User entered 'mRNA-1273 (mRNA-1273)'	Carlton Griffin (b) (4)	04 Jan 2021 16:19:17
	(b) (4)	

US3782028

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:20

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	04 Jan 2021 16:19:17

US3782028

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:20

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User entered empty.	System	04 Jan 2021 16:19:17

US3782028

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:20

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User entered empty.	System	04 Jan 2021 16:19:17

US3782028

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	04 Jan 2021 16:22:49

US3782028

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 04JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 04JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate. ' canceled (Site from DM).	(b) (4)	14 Jan 2021 12:55:59
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 04JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 04JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 17:41:40
User entered '4 Jan 2021'	Carlton Griffin (b) (4)	04 Jan 2021 16:22:49

US3782028

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '10:07'	(b) (4) Carlton Griffin (b) (4) (b) (4)	04 Jan 2021 16:22:49

US3782028

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User entered '4 Jan 2021 10:07'	System	04 Jan 2021 16:22:49

US3782028

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:48:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	04 Jan 2021 16:23:02

US3782028

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:48:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '4 Jan 2021'	(b) (4) Carlton Griffin (b) (4) (b) (4)	04 Jan 2021 16:23:02

US3782028

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:48:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '10:08'	(b) (4) Carlton Griffin (b) (4) (b) (4)	04 Jan 2021 16:23:02

US3782028

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:48:20

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:38:45
User entered '4 Jan 2021 10:08'	System	04 Jan 2021 16:23:02

US3782028

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:48:20

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:50:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User closed query 'Per DM CLR: Per Day 124 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 02:54:49
Query 'Per DM CLR: Per Day 124 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'participant was referring to procedure #1 ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	17 Mar 2021 15:44:35
User opened query 'Per DM CLR: Per Day 124 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:11:00
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:41:53
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 14:55:27
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	26 Feb 2021 14:55:27

US3782028

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:48:20

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:25:16
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	19 Feb 2021 19:14:37
	(b) (4)	

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:42:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:16
User entered 'USA-US125-2021-mRNA-1273-P301000002'	System	01 Mar 2021 15:54:11
User entered 'New'	(b) (4), (b) (6)	01 Mar 2021 15:54:11

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 03:11:21
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'tested while in the ED and was negative. ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	30 Mar 2021 18:20:19
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 23:55:23
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:42:18
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Feb 2021 00:41:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Feb 2021 00:41:59
Data point term sent to Coder	System	26 Feb 2021 15:06:33
User entered 'bilateral pulmonary embolus'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:42:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:42:24
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:42:26
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:17:17
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (21-Feb-2021). If not updating the start date, please clarify.' (Site from Safety). Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (21-Feb-2021). If not updating the start date, please clarify.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 17:18:03
DataPoint Un-verified.	Carlton Griffin (b) (4) (b) (4)	08 Mar 2021 19:50:48
User entered '21 Feb 2021' reason for change: Per Query Resolution	Carlton Griffin (b) (4) (b) (4)	08 Mar 2021 19:50:41
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (21-Feb-2021). If not updating the start date, please clarify.' (Site from Safety).	(b) (4), (b) (6)	06 Mar 2021 20:16:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:42:31
User entered '22 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:42:35
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:17:23
DataPoint Un-verified.	(b) (4), (b) (6)	15 Mar 2021 14:37:35
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Mar 2021 14:37:35
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' canceled (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 12:42:16
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 12:42:13
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:42:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:17:25
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	15 Mar 2021 14:37:35
DataPoint Un-verified.	(b) (4), (b) (6)	15 Mar 2021 14:37:35
User entered '25 Feb 2021' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Mar 2021 14:37:35
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). DataPoint Verified.	System	15 Mar 2021 14:31:34
	(b) (4), (b) (6)	02 Mar 2021 21:42:48
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:42:49
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:43:25
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:43:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:43:30
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:43:32
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:43:34
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:43:36
User entered '22 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:18:09
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'sent via email' (Site from Safety).	Carlton Griffin (b) (4) (b) (4)	08 Mar 2021 20:30:33
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	06 Mar 2021 20:20:12
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:43:41
User entered '25 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:43:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:43:45
User entered '2'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:43:48
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:43:51
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:43:53
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:43:55
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:44:02
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:44:04
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:44:07
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:44:08
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User closed query 'PV Query: Please provide results of Transthoracic echocardiogram and Vascular duplex studies.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:18:14
Query 'PV Query: Please provide results of Transthoracic echocardiogram and Vascular duplex studies.' answered with 'sent via email with discharge summary / hospital records' (Site from Safety).	Carlton Griffin (b) (4) (b) (4)	08 Mar 2021 20:30:51
User opened query 'PV Query: Please provide results of Transthoracic echocardiogram and Vascular duplex studies.' (Site from Safety).	(b) (4), (b) (6)	06 Mar 2021 20:17:58
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:44:12
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:17:42
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 14:46:32
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' answered with 'no new diagnostic evidence of resolution but ongoing need for Eliquis' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 14:37:52
DataPoint Un-verified.	(b) (4), (b) (6)	15 Mar 2021 14:31:34
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Mar 2021 14:31:34
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 12:42:27
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 17:32:46
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'this will not be fully recovered/resolved as the participant will not be rescanned to evaluate the occurrence of the pulmonary emboli. ' (Site from Safety).	Carlton Griffin (b) (4) (b) (4)	09 Mar 2021 17:13:42

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Mar 2021 20:17:15
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:44:15
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:18:45
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	15 Mar 2021 14:38:16
DataPoint Un-verified.	(b) (4), (b) (6)	15 Mar 2021 14:38:16
User entered 'no new diagnostic evidence of resolution but ongoing need for Eliquis' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Mar 2021 14:38:16
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	15 Mar 2021 14:31:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:44:17
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User closed query 'Per DM CLR: Narrative = SYNCOPE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 03:14:27
Query 'Per DM CLR: Narrative = SYNCOPE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' answered with 'no. this is a symptom of this AE (bilateral pulmonary embolus)' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	29 Mar 2021 14:06:38
User opened query 'Per DM CLR: Narrative = SYNCOPE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 04:18:50
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 17:32:50
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'post op hip replacement in December 2020' (Site from Safety).	Carlton Griffin (b) (4) (b) (4)	08 Mar 2021 20:22:16
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	06 Mar 2021 20:17:46
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:44:20
User entered 'SOB started 2/21/21. Syncope with LOC on 2/22 - transf to hospital via EMS with 02 Sat 80%, HR 130's. Diagnostics revealed pulm embolus bilaterally (s/p THR Dec 2020). See procedures and medications for treatments. Pt discharged 2/25 in stable condition. Not tested for COVID by clinic but was tested in hospital with negative result.'	(b) (4), (b) (6)	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 15:05:49

US3782028

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:20

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 15:05:49

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:48:20

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:50:58
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:44:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	Amber Massey (b) (4)	19 Aug 2020 13:42:33

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Aug 2020 13:44:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 13:44:23
Data point term sent to Coder	System	19 Aug 2020 13:43:18
User entered 'synthroid'	Amber Massey (b) (4) (b) (4)	19 Aug 2020 13:43:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered 'No (N)'	Amber Massey (b) (4)	19 Aug 2020 13:43:11
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered 'hypothyroidism'	Amber Massey (b) (4)	19 Aug 2020 13:43:11
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered '200'	Amber Massey (b) (4)	19 Aug 2020 13:43:11
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User closed query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 13:10:56
Query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 18:55:07
User entered 'ug (ug)' reason for change: Per Query Resolution	(b) (4), (b) (6)	05 Oct 2020 18:55:00
User opened query 'Per CDM: mcg (ug) is an option in the drop down box provided. Please update accordingly using the drop down box. Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 18:33:22
User entered 'Other (OTHER)'	Amber Massey (b) (4) (b) (4)	19 Aug 2020 13:43:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty; reason for change Per Query Resolution	(b) (4) (b) (4), (b) (6)	05 Oct 2020 18:55:00
User entered 'mcg'	Amber Massey (b) (4) (b) (4)	19 Aug 2020 13:43:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered 'once daily (QD)'	Amber Massey (b) (4)	19 Aug 2020 13:43:11
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:08:46
User entered empty.	Amber Massey (b) (4) (b) (4)	19 Aug 2020 13:43:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Massey (b) (4)	19 Aug 2020 13:43:11
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	19 Aug 2020 13:43:11
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:52:50
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Ongoing medication; taken within 28 days of study start.' (Site from System).	Amber Massey (b) (4) (b) (4)	19 Aug 2020 13:44:12
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 13:43:11
User entered 'un UNK 1990'	Amber Massey (b) (4) (b) (4)	19 Aug 2020 13:43:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered '0'	Amber Massey (b) (4)	19 Aug 2020 13:43:11
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered 'Yes (Y)'	Amber Massey (b) (4)	19 Aug 2020 13:43:11
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	19 Aug 2020 13:43:11
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered 'No (N)'	Amber Massey (b) (4)	19 Aug 2020 13:43:11
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 13:43:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 13:43:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 13:43:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Sep 2020 15:29:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 15:29:42
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	05 Sep 2020 15:28:32 05 Sep 2020 15:27:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:36:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 14:36:00
Data point term sent to Coder User entered 'Aleve'	System Amber Massey (b) (4) (b) (4)	19 Aug 2020 13:44:21 19 Aug 2020 13:43:48

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered 'No (N)'	Amber Massey (b) (4)	19 Aug 2020 13:43:48
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User closed query 'Per CDM: This appears to be the Dose and not the Indication. Please review and update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 12:10:19
Query 'Per CDM: This appears to be the Dose and not the Indication. Please review and update accordingly' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 15:28:08
User entered 'osteoarthritis' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Sep 2020 15:27:59
User opened query 'Per CDM: This appears to be the Dose and not the Indication. Please review and update accordingly' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 12:30:57
User entered '220'	Amber Massey (b) (4) (b) (4)	19 Aug 2020 13:43:48

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered '220'	Amber Massey (b) (4)	19 Aug 2020 13:43:48
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered 'mg (mg)'	Amber Massey (b) (4)	19 Aug 2020 13:43:48
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:08:46
User entered empty.	Amber Massey (b) (4) (b) (4)	19 Aug 2020 13:43:48

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered 'as needed (PRN)'	Amber Massey (b) (4)	19 Aug 2020 13:43:48
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	19 Aug 2020 13:43:48
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Massey (b) (4)	19 Aug 2020 13:43:48
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	19 Aug 2020 13:43:48
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Aug 2020 18:52:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Amber Massey (b) (4)	19 Aug 2020 13:44:04
answered with 'Ongoing medication; taken within 28 days of study start.' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 13:43:48
User entered 'un UNK 2019'	Amber Massey (b) (4)	19 Aug 2020 13:43:48
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered '0'	Amber Massey (b) (4)	19 Aug 2020 13:43:48
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered 'Yes (Y)'	Amber Massey (b) (4)	19 Aug 2020 13:43:48
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	19 Aug 2020 13:43:48
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered 'No (N)'	Amber Massey (b) (4)	19 Aug 2020 13:43:48
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 13:43:48

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 13:43:48

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 13:43:48

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 12:35:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 12:35:36
Data point term sent to Coder	System	14 Oct 2020 12:34:46
User entered 'influenza vaccine'	Carlton Griffin (b) (4)	14 Oct 2020 12:33:58

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	14 Oct 2020 12:33:58

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'influenza prophylaxis'	Carlton Griffin (b) (4)	14 Oct 2020 12:33:58

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0.5'	Carlton Griffin (b) (4)	14 Oct 2020 12:33:58

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'mL (mL)'	Carlton Griffin (b) (4)	14 Oct 2020 12:33:58

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	Carlton Griffin (b) (4)	14 Oct 2020 12:33:58

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'once (ONCE)'	Carlton Griffin (b) (4)	14 Oct 2020 12:33:58

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	Carlton Griffin (b) (4)	14 Oct 2020 12:33:58

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Intramuscular (INTRAMUSCULAR)'	Carlton Griffin (b) (4)	14 Oct 2020 12:33:58

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	Carlton Griffin (b) (4)	14 Oct 2020 12:33:58

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:20

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '7 Oct 2020'	(b) (4) Carlton Griffin (b) (4)	14 Oct 2020 12:33:58

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	Carlton Griffin (b) (4)	14 Oct 2020 12:33:58

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	Carlton Griffin (b) (4)	14 Oct 2020 12:33:58

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '7 Oct 2020'	Carlton Griffin (b) (4)	14 Oct 2020 12:33:58

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	Carlton Griffin (b) (4)	14 Oct 2020 12:33:58

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:43
User entered empty.	System	14 Oct 2020 12:33:58

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:43
User entered empty.	System	14 Oct 2020 12:33:58

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:43
User entered empty.	System	14 Oct 2020 12:33:58

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Dec 2020 10:21:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 10:21:56
Data point term sent to Coder	System	21 Dec 2020 19:24:50
User entered 'celebrex'	(b) (4), (b) (6)	21 Dec 2020 19:24:41

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:24:41

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'right hip replacement (post-op pain)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:24:41

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '100'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:24:41

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:24:41

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4)	21 Dec 2020 19:24:41

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:24:41

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:24:41

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:24:41

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 19:24:41

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:20

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:24:41

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:24:41

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	14 Jan 2021 17:24:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 19:24:41

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '9 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	14 Jan 2021 17:24:47
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 19:24:41

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:24:41

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:25
User entered '2'	System	21 Dec 2020 19:24:41

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:25
User entered '1'	System	21 Dec 2020 19:24:41

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:25
User entered '804 (804)'	System	21 Dec 2020 19:24:41

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:30
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
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.	Coder Import (b) (4)	22 Dec 2020 00:21:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 00:21:41
Data point term sent to Coder	System	21 Dec 2020 19:34:58
User entered 'baby aspirin'	(b) (4), (b) (6)	21 Dec 2020 19:34:09

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:30
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:34:09

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:30
User closed query 'Per DM CLR: Please note that there is no AE(POST OP PAIN) that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 14:24:55
Query 'Per DM CLR: Please note that there is no AE(POST OP PAIN) that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'baby aspirin is not indicated to treat an AE. this is prophylaxis for clotting in the post-op period' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	27 Jan 2021 20:06:24
User opened query 'Per DM CLR: Please note that there is no AE(POST OP PAIN) that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 11:32:03
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:08:46
User entered 'right hip replacement (post-op anticoagulation)'	(b) (4), (b) (6)	21 Dec 2020 19:34:09

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:30
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '81'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:34:09

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:30
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Dec 2020 19:34:09

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:30
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 19:34:09

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:30
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:34:09

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:30
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:34:09

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:30
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:34:09

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:30
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 19:34:09

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:20

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:30
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:34:09

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:30
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4), (b) (6)	21 Dec 2020 19:34:09

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
Signature has been broken.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:15:46
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	26 Feb 2021 15:15:46
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:34:09

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:30
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
Signature has been broken.	(b) (4), (b) (6)	26 Feb 2021 15:15:46
User entered '22 Feb 2021' reason for change: New Information	(b) (4), (b) (6)	26 Feb 2021 15:15:46
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 19:34:09

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:30
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:34:09

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:30
User entered '2'	System	21 Dec 2020 19:34:09

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:30
User entered '1'	System	21 Dec 2020 19:34:09

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:30
User entered '804 (804)'	System	21 Dec 2020 19:34:09

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:20

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 22:02:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 22:02:48
Data point term sent to Coder	System	21 Dec 2020 19:38:01
User entered 'flexeril'	(b) (4), (b) (6)	21 Dec 2020 19:37:18

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:37:18

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'right hip replacement (post-op pain)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:37:18

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '5'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:37:18

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:37:18

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 19:37:18

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:37:18

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 19:37:18

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:37:18

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 19:37:18

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:20

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:37:18

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:37:18

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)' reason for change: New Information	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 17:25:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 19:37:18

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '30 Dec 2020' reason for change: New Information	(b) (4)	14 Jan 2021 17:25:22
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 19:37:18

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:37:18

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:36
User entered empty.	System	21 Dec 2020 19:37:18

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:36
User entered empty.	System	21 Dec 2020 19:37:18

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:36
User entered empty.	System	21 Dec 2020 19:37:18

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Dec 2020 18:50:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 18:50:42
Data point term sent to Coder	System	21 Dec 2020 19:40:03
User entered 'senokot (sennosides 8.6 mg)'	(b) (4), (b) (6)	21 Dec 2020 19:39:37

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:39:37

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'right hip replacement (prophylaxis post op constipation)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:39:37

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:39:37

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	21 Dec 2020 19:39:37

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:39:37

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:39:37

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 19:39:37

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:39:37

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:39:37

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:20

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:39:37

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:39:37

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)' reason for change: New Information	Carlton Griffin (b) (4)	04 Jan 2021 16:27:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 19:39:37

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '02 Jan 2021' reason for change: New Information	(b) (4) Carlton Griffin (b) (4)	04 Jan 2021 16:27:05
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 19:39:37

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:39:37

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:32
User entered '2'	System	21 Dec 2020 19:39:37

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:32
User entered '1'	System	21 Dec 2020 19:39:37

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:32
User entered '804 (804)'	System	21 Dec 2020 19:39:37

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Dec 2020 21:33:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:42
Data point term sent to Coder	System	21 Dec 2020 19:42:06
User entered 'Tylenol'	(b) (4), (b) (6)	21 Dec 2020 19:41:39

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:41:39

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'right hip replacement (post-op pain)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:41:39

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '1000'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:41:39

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:41:39

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:41:39

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:41:39

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:41:39

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:41:39

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:41:39

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:20

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

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:41:39

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:41:39

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:41:39

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:41:39

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:41:39

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 19:41:39

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 19:41:39

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 19:41:39

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:20

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
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, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Dec 2020 18:19:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Dec 2020 18:19:41
Data point term sent to Coder	System	21 Dec 2020 19:57:27
User entered 'prilosec'	(b) (4), (b) (6)	21 Dec 2020 19:57:10

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:57:10

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'right hip replacement (GI prophylaxis)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:57:10

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '20'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:57:10

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:57:10

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 19:57:10

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:57:10

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:57:10

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:57:10

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:57:10

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:20

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:57:10

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:57:10

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:25:16
Signature has been broken.	(b) (4)	
	Carlton Griffin (b) (4)	12 Feb 2021 19:59:10
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Carlton Griffin (b) (4)	12 Feb 2021 19:59:10
	(b) (4)	
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 19:57:10

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:18
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:25:16
Signature has been broken.	Carlton Griffin (b) (4)	12 Feb 2021 19:59:10
User entered '28 Jan 2021' reason for change: New Information	Carlton Griffin (b) (4)	12 Feb 2021 19:59:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 19:57:10

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:18
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:57:10

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:18
User entered '1'	System	21 Dec 2020 19:57:10

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:18
User entered '1'	System	21 Dec 2020 19:57:10

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:18
User entered '804 (804)'	System	21 Dec 2020 19:57:10

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:04
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Dec 2020 11:55:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 11:55:45
Data point term sent to Coder	System	21 Dec 2020 19:59:32
User entered 'oxycodone'	(b) (4), (b) (6)	21 Dec 2020 19:59:20

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:04
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:59:20

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:04
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'right hip replacement post op pain'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:59:20

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:04
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '10'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:59:20

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:04
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:59:20

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:04
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 19:59:20

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:04
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'as needed (PRN)'	(b) (4), (b) (6)	21 Dec 2020 19:59:20

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:04
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 19:59:20

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:04
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:59:20

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:04
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 19:59:20

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:04
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:59:20

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:04
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4), (b) (6)	21 Dec 2020 19:59:20

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:04
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)' reason for change: New Information	Carlton Griffin (b) (4)	04 Jan 2021 16:27:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 19:59:20

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:04
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '23 Dec 2020' reason for change: New Information	(b) (4)	
	Carlton Griffin (b) (4)	04 Jan 2021 16:27:39
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:59:20

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:04
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:59:20

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:04
User entered empty.	System	21 Dec 2020 19:59:20

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:04
User entered empty.	System	21 Dec 2020 19:59:20

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:04
User entered empty.	System	21 Dec 2020 19:59:20

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, PRODUCT: ANESTHETICS, LOCAL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Dec 2020 19:03:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 19:03:48
Data point term sent to Coder	System	21 Dec 2020 20:04:35
User entered 'spinal anesthesia'	(b) (4), (b) (6)	21 Dec 2020 20:03:36

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:03:36

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'right hip replacment'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:03:36

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:03:36

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:03:36

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'unknown'	(b) (4), (b) (6)	21 Dec 2020 20:03:36

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:03:36

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:03:36

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:03:36

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'spinal'	(b) (4), (b) (6)	21 Dec 2020 20:03:36

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:20

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:03:36

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '0'	(b) (4), (b) (6)	21 Dec 2020 20:03:36

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:03:36

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:03:36

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:03:36

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:10
User entered empty.	System	21 Dec 2020 20:03:36

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:10
User entered empty.	System	21 Dec 2020 20:03:36

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:00:10
User entered empty.	System	21 Dec 2020 20:03:36

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:46:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 08:04:25
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 Mar 2021 08:04:25
Data point term sent to Coder	System	26 Feb 2021 15:37:22
User entered 'heparin'	(b) (4), (b) (6)	26 Feb 2021 15:36:27

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:46:11
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:36:27

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:46:13
User entered 'bilateral pulmonary embolus'	(b) (4), (b) (6)	26 Feb 2021 15:36:27

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:46:15
User entered 'UNK'	(b) (4), (b) (6)	26 Feb 2021 15:36:27

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:47:36
User entered 'Other (OTHER)'	(b) (4), (b) (6)	26 Feb 2021 15:36:27

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:47:38
User entered 'units'	(b) (4), (b) (6)	26 Feb 2021 15:36:27

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:47:40
User entered 'other (OTHER)'	(b) (4), (b) (6)	26 Feb 2021 15:36:27

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:47:45
User entered 'continuous via titrated IV drip'	(b) (4), (b) (6)	26 Feb 2021 15:36:27

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:47:47
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4), (b) (6)	26 Feb 2021 15:36:27

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:47:50
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:36:27

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:52:26
User entered '22 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:36:27

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:52:27
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 15:36:27

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:25:05
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:36:27

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:25:09
User entered '23 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:36:27

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:29
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:25:16
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:36:27

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:29
User entered empty.	System	26 Feb 2021 15:36:27

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:29
User entered empty.	System	26 Feb 2021 15:36:27

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:29
User entered empty.	System	26 Feb 2021 15:36:27

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:26:03
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) (b) (4)	02 Mar 2021 07:44:21
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 Mar 2021 07:44:21
Data point term sent to Coder	System	26 Feb 2021 15:37:22
User entered 'fentanyl'	(b) (4), (b) (6)	26 Feb 2021 15:37:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:26:06
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:37:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:26:08
User entered 'EKOS catheter procedure'	(b) (4), (b) (6)	26 Feb 2021 15:37:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:26:10
User entered '25'	(b) (4), (b) (6)	26 Feb 2021 15:37:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:26:13
User entered 'ug (ug)'	(b) (4), (b) (6)	26 Feb 2021 15:37:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:26:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:37:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:26:20
User entered 'once (ONCE)'	(b) (4), (b) (6)	26 Feb 2021 15:37:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:26:22
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:37:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:26:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	26 Feb 2021 15:37:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:26:28
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:37:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:26:32
User entered '22 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:37:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:26:36
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 15:37:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:26:41
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:37:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:26:42
User entered '22 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:37:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:35
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:26:47
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:37:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:35
User entered empty.	System	26 Feb 2021 15:37:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:35
User entered empty.	System	26 Feb 2021 15:37:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:35
User entered empty.	System	26 Feb 2021 15:37:11

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:26:57
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) (b) (4)	02 Mar 2021 07:44:22
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 Mar 2021 07:44:22
Data point term sent to Coder	System	26 Feb 2021 15:38:23
User entered 'fentanyl'	(b) (4), (b) (6)	26 Feb 2021 15:37:49

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:27:24
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:37:49

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:27:28
User entered 'ekos catheter procedure'	(b) (4), (b) (6)	26 Feb 2021 15:37:49

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:27:31
User entered '50'	(b) (4), (b) (6)	26 Feb 2021 15:37:49

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:27:33
User entered 'ug (ug)'	(b) (4), (b) (6)	26 Feb 2021 15:37:49

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:27:35
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:37:49

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:27:37
User entered 'once (ONCE)'	(b) (4), (b) (6)	26 Feb 2021 15:37:49

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:27:42
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:37:49

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:27:46
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	26 Feb 2021 15:37:49

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:27:49
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:37:49

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:27:52
User entered '22 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:37:49

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:27:56
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 15:37:49

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:27:59
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:37:49

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:28:01
User entered '22 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:37:49

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:28:03
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:37:49

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:02
User entered empty.	System	26 Feb 2021 15:37:49

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:02
User entered empty.	System	26 Feb 2021 15:37:49

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:02
User entered empty.	System	26 Feb 2021 15:37:49

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:20

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Mar 2021 07:54:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:54:01
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:28:13
Data point term sent to Coder	System	26 Feb 2021 15:39:24
User entered 'midazolam'	(b) (4), (b) (6)	26 Feb 2021 15:38:24

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:28:17
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:38:24

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:28:20
User entered 'EKOS catheter procedure'	(b) (4), (b) (6)	26 Feb 2021 15:38:24

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:28:28
User entered '0.5'	(b) (4), (b) (6)	26 Feb 2021 15:38:24

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:28:30
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Feb 2021 15:38:24

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:28:32
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:38:24

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:28:35
User entered 'once (ONCE)'	(b) (4), (b) (6)	26 Feb 2021 15:38:24

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:28:37
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:38:24

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:28:39
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	26 Feb 2021 15:38:24

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:28:42
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:38:24

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:28:44
User entered '22 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:38:24

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:28:47
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 15:38:24

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:28:53
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:38:24

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:28:55
User entered '22 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:38:24

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:28:57
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:38:24

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:55
User entered empty.	System	26 Feb 2021 15:38:24

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:55
User entered empty.	System	26 Feb 2021 15:38:24

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:55
User entered empty.	System	26 Feb 2021 15:38:24

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Mar 2021 05:10:47
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 Mar 2021 05:10:47
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:29:09
Data point term sent to Coder	System	26 Feb 2021 15:39:24
User entered 'Lidocaine 1%'	(b) (4), (b) (6)	26 Feb 2021 15:39:06

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:29:11
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:39:06

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:29:15
User entered 'EKOS catheter procedure'	(b) (4), (b) (6)	26 Feb 2021 15:39:06

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:29:20
User entered '20'	(b) (4), (b) (6)	26 Feb 2021 15:39:06

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:29:24
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Feb 2021 15:39:06

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:29:26
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:39:06

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:29:29
User entered 'once (ONCE)'	(b) (4), (b) (6)	26 Feb 2021 15:39:06

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:29:31
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:39:06

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:29:35
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	26 Feb 2021 15:39:06

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:29:36
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:39:06

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:29:40
User entered '22 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:39:06

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:29:42
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 15:39:06

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:29:46
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:39:06

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:29:48
User entered '22 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:39:06

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:29:52
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:39:06

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:10
User entered empty.	System	26 Feb 2021 15:39:06

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:10
User entered empty.	System	26 Feb 2021 15:39:06

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:10
User entered empty.	System	26 Feb 2021 15:39:06

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:48:20

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:53:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: ENZYMES, PRODUCT: ALTEPLASE, PRODUCTSYNONYM: CATHFLO ACTIVASE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:58:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:58:54
Data point term sent to Coder	System	18 Mar 2021 13:42:41
DataPoint Un-verified.	Carlton Griffin (b) (4)	18 Mar 2021 13:42:25
Coding entries removed.	(b) (4) Carlton Griffin (b) (4)	18 Mar 2021 13:42:25
User entered 'ATEPLASE (cathoflo activase)' reason for change: Per Query Resolution	Carlton Griffin (b) (4)	18 Mar 2021 13:42:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: ENZYMES, PRODUCT: ALTEPLASE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Mar 2021 07:44:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 07:44:13
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:30:09
Data point term sent to Coder	System	26 Feb 2021 15:40:25
User entered 'Ateplase'	(b) (4), (b) (6)	26 Feb 2021 15:39:43

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:30:14
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:39:43

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 02:55:35
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'please advise. con meds 13-17 are all indicated for this procedure. only alternative would be to revise indication to her AE of bilateral pulmonary embolus. ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	05 Apr 2021 15:33:40
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 07:47:04
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:30:16
User entered 'EKOS catheter procedure'	(b) (4), (b) (6)	26 Feb 2021 15:39:43

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
User closed query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4)	06 Apr 2021 02:55:37
Query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'per medical record, this was the dose given. but added cathflo activase to name of medication ' (Site from DM).	Carlton Griffin (b) (4)	18 Mar 2021 13:43:36
User opened query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 01:59:08
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:30:18
User entered '0.88'	(b) (4), (b) (6)	26 Feb 2021 15:39:43

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:30:19
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Feb 2021 15:39:43

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:30:21
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:39:43

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:30:23
User entered 'once (ONCE)'	(b) (4), (b) (6)	26 Feb 2021 15:39:43

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:48:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:30:26
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:39:43

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:30:27
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	26 Feb 2021 15:39:43

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:30:29
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:39:43

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:48:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:30:33
User entered '22 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:39:43

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:30:42
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 15:39:43

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:31:15
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:39:43

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:31:17
User entered '22 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:39:43

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:17
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:31:19
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:39:43

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:17
User entered empty.	System	26 Feb 2021 15:39:43

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:17
User entered empty.	System	26 Feb 2021 15:39:43

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:58:17
User entered empty.	System	26 Feb 2021 15:39:43

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:48:20

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:02
User closed query 'Per DM CLR: Please confirm if this was given for Con Prco #2 or #4. If yes, please review start date of this Con Med (23 FEB 2021) as it was given after the Con Proc date (22 FEB 2021). Review and update dates if applicable. Otherwise, provide comment. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Spyros Kalams (b) (4)	16 Apr 2021 13:27:12 09 Apr 2021 01:06:17
Query 'Per DM CLR: Please confirm if this was given for Con Prco #2 or #4. If yes, please review start date of this Con Med (23 FEB 2021) as it was given after the Con Proc date (22 FEB 2021). Review and update dates if applicable. Otherwise, provide comment. ' answered with 'medication not given for con procedure #2 or #4. not given for any procedure listed as transthoracic echocardiogram is a diagnostic test and not a procedure. the dates listed below for this medication are correct. ' (Site from DM). User opened query 'Per DM CLR: Please confirm if this was given for Con Prco #2 or #4. If yes, please review start date of this Con Med (23 FEB 2021) as it was given after the Con Proc date (22 FEB 2021). Review and update dates if applicable. Otherwise, provide comment. ' (Site from DM).	Carlton Griffin (b) (4) (b) (4) (b) (4), (b) (6)	18 Mar 2021 13:51:05 18 Mar 2021 02:01:05
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: ULTRASOUND CONTRAST MEDIA, ATC: ULTRASOUND CONTRAST MEDIA, PRODUCT: PERFLUTREN, PRODUCTSYNONYM: DEFINITY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 22:16:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. DataPoint Verified.	Coder Import (b) (4) (b) (4) (b) (4), (b) (6)	04 Mar 2021 22:16:39 03 Mar 2021 18:31:37
Data point term sent to Coder User entered 'definity'	System (b) (4), (b) (6)	26 Feb 2021 15:40:25 26 Feb 2021 15:40:22

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:31:39
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:40:22

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:31:42
User entered 'transthoracic echocardiogram'	(b) (4), (b) (6)	26 Feb 2021 15:40:22

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:31:44
User entered '2.2'	(b) (4), (b) (6)	26 Feb 2021 15:40:22

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:31:47
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Feb 2021 15:40:22

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:31:50
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:40:22

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:31:52
User entered 'once (ONCE)'	(b) (4), (b) (6)	26 Feb 2021 15:40:22

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:48:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:31:54
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:40:22

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:31:56
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	26 Feb 2021 15:40:22

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:31:59
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:40:22

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:48:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:32:03
User entered '23 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:40:22

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:32:05
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 15:40:22

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:32:07
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:40:22

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:32:09
User entered '23 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:40:22

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:02
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:32:11
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:40:22

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:02
User entered empty.	System	26 Feb 2021 15:40:22

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:02
User entered empty.	System	26 Feb 2021 15:40:22

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:02
User entered empty.	System	26 Feb 2021 15:40:22

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:48:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:32:22
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) (b) (4)	27 Feb 2021 00:50:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Feb 2021 00:50:58
Data point term sent to Coder	System	26 Feb 2021 15:41:26
User entered 'ceftriaxone'	(b) (4), (b) (6)	26 Feb 2021 15:41:07

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:54:01
User closed query 'Per DM CLR: Prophylaxis = No. However, there is no MH or AE condition that matches this indication. Please review and confirm if this was given as a prophylaxis? If yes, please update as appropriate. Otherwise, provide comment.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 16:41:32
Query 'Per DM CLR: Prophylaxis = No. However, there is no MH or AE condition that matches this indication. Please review and confirm if this was given as a prophylaxis? If yes, please update as appropriate. Otherwise, provide comment.' answered with 'changed to yes, however participant was not diagnosed with sepsis. medication was given in the ER before accurate diagnosis of PE ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:46:27
DataPoint Un-verified.	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:44:55
User entered 'Yes (Y)' reason for change: Per Query Resolution	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:44:55
User opened query 'Per DM CLR: Prophylaxis = No. However, there is no MH or AE condition that matches this indication. Please review and confirm if this was given as a prophylaxis? If yes, please update as appropriate. Otherwise, provide comment.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 02:02:33
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:32:23
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:41:07

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:32:31
User entered 'presumptive sepsis'	(b) (4), (b) (6)	26 Feb 2021 15:41:07

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:32:34
User entered '2'	(b) (4), (b) (6)	26 Feb 2021 15:41:07

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:32:40
User entered 'g (g)'	(b) (4), (b) (6)	26 Feb 2021 15:41:07

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:32:43
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:41:07

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:32:45
User entered 'once (ONCE)'	(b) (4), (b) (6)	26 Feb 2021 15:41:07

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:48:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:32:47
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:41:07

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:32:52
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	26 Feb 2021 15:41:07

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:32:55
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:41:07

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:48:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:32:56
User entered '22 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:41:07

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:32:58
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 15:41:07

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:33:01
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:41:07

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:33:05
User entered '22 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:41:07

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:33:07
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:41:07

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:18
User entered empty.	System	26 Feb 2021 15:41:07

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:18
User entered empty.	System	26 Feb 2021 15:41:07

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:18
User entered empty.	System	26 Feb 2021 15:41:07

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:48:20

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:23
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:33:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Feb 2021 00:26:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Feb 2021 00:26:57
Data point term sent to Coder	System	26 Feb 2021 15:42:29
User entered 'azithromycin'	(b) (4), (b) (6)	26 Feb 2021 15:41:40

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:23
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:54:10
User closed query 'Per DM CLR: Prophylaxis = No. However, there is no MH or AE condition that matches this indication. Please review and confirm if this was given as a prophylaxis? If yes, please update as appropriate. Otherwise, provide comment.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 16:40:16
Query 'Per DM CLR: Prophylaxis = No. However, there is no MH or AE condition that matches this indication. Please review and confirm if this was given as a prophylaxis? If yes, please update as appropriate. Otherwise, provide comment.' answered with 'changed to yes, however participant was not diagnosed with sepsis. medication was given in the ER before accurate diagnosis of PE ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:46:48
DataPoint Un-verified.	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:46:40
User entered 'Yes (Y)' reason for change: Per Query Resolution	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:46:40
User opened query 'Per DM CLR: Prophylaxis = No. However, there is no MH or AE condition that matches this indication. Please review and confirm if this was given as a prophylaxis? If yes, please update as appropriate. Otherwise, provide comment.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 02:02:53
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:33:21
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:41:40

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:23
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:33:37
User entered 'presumptive sepsis'	(b) (4), (b) (6)	26 Feb 2021 15:41:40

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:23
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:33:42
User entered '500'	(b) (4), (b) (6)	26 Feb 2021 15:41:40

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:23
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:33:44
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Feb 2021 15:41:40

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:23
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:33:48
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:41:40

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:23
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:41:11
User entered 'once (ONCE)'	(b) (4), (b) (6)	26 Feb 2021 15:41:40

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:48:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:23
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:41:16
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:41:40

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:23
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:41:20
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	26 Feb 2021 15:41:40

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:23
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:41:22
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:41:40

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:48:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:23
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:41:24
User entered '22 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:41:40

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:23
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:41:28
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 15:41:40

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:23
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:41:29
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:41:40

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:23
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:41:31
User entered '22 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:41:40

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:23
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:41:33
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:41:40

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:23
User entered empty.	System	26 Feb 2021 15:41:40

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:23
User entered empty.	System	26 Feb 2021 15:41:40

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:23
User entered empty.	System	26 Feb 2021 15:41:40

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:48:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:42:43
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 12:47:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 12:47:47
Data point term sent to Coder	System	26 Feb 2021 15:42:29
User entered 'apixaban'	(b) (4), (b) (6)	26 Feb 2021 15:42:14

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:42:47
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:42:14

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:42:53
User entered 'bilateral pulmonary embolus'	(b) (4), (b) (6)	26 Feb 2021 15:42:14

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:42:57
User entered '10'	(b) (4), (b) (6)	26 Feb 2021 15:42:14

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:43:01
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Feb 2021 15:42:14

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:43:03
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:42:14

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:43:07
User entered 'twice daily (BID)'	(b) (4), (b) (6)	26 Feb 2021 15:42:14

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:48:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:43:10
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:42:14

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:43:13
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Feb 2021 15:42:14

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:43:15
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:42:14

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:48:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:43:18
User entered '23 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:42:14

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:43:20
User entered '0'	(b) (4), (b) (6)	26 Feb 2021 15:42:14

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:54:20
DataPoint Un-verified.	Carlton Griffin (b) (4)	18 Mar 2021 13:30:11
User entered 'No (N)' reason for change: New Information	(b) (4) Carlton Griffin (b) (4)	18 Mar 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:43:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 15:42:14

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:54:21
DataPoint Un-verified.	Carlton Griffin (b) (4)	18 Mar 2021 13:30:11
User entered '01 Mar 2021' reason for change: New Information	(b) (4) Carlton Griffin (b) (4)	18 Mar 2021 13:30:11
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:43:27
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:42:14

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:09
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 18:43:30
User entered 'No (N)'	(b) (4), (b) (6)	26 Feb 2021 15:42:14

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:09
User entered '2'	System	26 Feb 2021 15:42:14

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:09
User entered '1'	System	26 Feb 2021 15:42:14

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:59:09
User entered '804 (804)'	System	26 Feb 2021 15:42:14

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:48:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:54:55
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 13:33:38
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 Mar 2021 13:33:38
Data point term sent to Coder	System	18 Mar 2021 13:32:27
User entered 'apixaban'	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:31:29

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:48:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:54:57
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:31:29

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:54:59
User entered 'BILATeral PULMONARY EMBOLUS' reason for change: Data Entry Error	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:31:49
User entered 'bilat. pulmonary embolus'	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:31:29

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:48:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:55:01
User entered '5'	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:31:29

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:48:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:55:02
User entered 'mg (mg)'	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:31:29

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:48:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:55:06
User entered empty.	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:31:29

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:48:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:55:10
User entered 'twice daily (BID)'	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:31:29

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:48:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:55:11
User entered empty.	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:31:29

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:48:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:55:13
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:31:29

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:48:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:55:15
User entered empty.	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:31:29

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:48:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is after the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 07:38:20
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
Query 'Per DM CLR: Con Med start date is after the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' answered with 'start date of the con med is correct ' (Site from DM).	Carlton Griffin (b) (4)	05 Apr 2021 15:24:34
User opened query 'Per DM CLR: Con Med start date is after the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 07:46:38
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence.	(b) (4), (b) (6)	04 Apr 2021 07:46:19
' canceled (Site from DM).		
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Otherwise, provide clarification for this occurrence.	(b) (4), (b) (6)	04 Apr 2021 07:45:42
' (Site from DM).		
Query 'US3782028	(b) (4), (b) (6)	04 Apr 2021 07:45:38
' canceled (Site from DM).		
User opened query 'US3782028	(b) (4), (b) (6)	04 Apr 2021 07:45:36
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:55:17
User entered '02 Mar 2021'	Carlton Griffin (b) (4)	18 Mar 2021 13:31:29
	(b) (4)	

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:48:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:55:18
User entered '0'	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:31:29

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:48:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:55:20
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:31:29

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:48:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:55:21
User entered empty.	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:31:29

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:48:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:55:23
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 13:31:29

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:48:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Mar 2021 13:31:29

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 13:31:29

US3782028

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:48:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Mar 2021 13:31:29

US3782028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:48:20

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:50:58
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:45:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Dec 2020 16:46:51

US3782028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:48:20

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	19 Dec 2020 16:47:19

US3782028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:48:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User closed query 'Per CDM: Right HIP Replacement indication is recorded as Medical history. Please review and update the Medical history as appropriate. Thank you.' (Site from DM).	(b) (4)	
Query 'Per CDM: Right HIP Replacement indication is recorded as Medical history. Please review and update the Medical history as appropriate. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 12:35:26
User opened query 'Per CDM: Right HIP Replacement indication is recorded as Medical history. Please review and update the Medical history as appropriate. Thank you.' (Site from DM).	Carlton Griffin (b) (4)	28 Dec 2020 22:02:48
User entered 'right hip replacement'	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 08:24:22
	(b) (4), (b) (6)	19 Dec 2020 16:47:19

US3782028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered 'Medical History (MH)'	(b) (4) (b) (4), (b) (6)	19 Dec 2020 16:47:19

US3782028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:48:20

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:08:46
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 16:47:19

US3782028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:48:20

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:35:18
User entered '22 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:12:37

US3782028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:48:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:35:22
User entered 'CT angiogram chest'	(b) (4), (b) (6)	26 Feb 2021 15:12:37

US3782028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:35:23
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	26 Feb 2021 15:12:37

US3782028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:48:20

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:55
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:35:26
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:12:37

US3782028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:48:20

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:35:36
User entered '25 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:12:54

US3782028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:48:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:35:40
User entered 'vascular duplex studies'	(b) (4), (b) (6)	26 Feb 2021 15:12:54

US3782028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:35:42
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	26 Feb 2021 15:12:54

US3782028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:48:20

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:39:58
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:35:45
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:12:54

US3782028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:48:20

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:35:56
User entered '22 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 15:13:07

US3782028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:48:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:35:59
User entered 'EKOS catheter'	(b) (4), (b) (6)	26 Feb 2021 15:13:07

US3782028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:48:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:36:01
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	26 Feb 2021 15:13:07

US3782028

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:48:20

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:40:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 19:36:03
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 15:13:07

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:05
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'USA-US125-2021-MRNA-1273-P301000002'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:08
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Yes (Y)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

Death

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:10
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Yes (Y)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:46
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:44
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Spyros'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Kalams'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered '1161 21st Avenue South'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Nashville'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:39:03
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered '37232'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 17:23:12
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:39:05
User entered 'US'	System	01 Mar 2021 15:54:37

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Mar 2021 15:00:36
User entered '2'	System	09 Mar 2021 17:23:24
User entered '1'	System	01 Mar 2021 15:54:37

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:05
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'USA-US125-2021-MRNA-1273-P301000002'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:08
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Yes (Y)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:10
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Yes (Y)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:46
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:44
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Spyros'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Kalams'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered '1161 21st Avenue South'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Nashville'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:39:03
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered '37232'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 17:23:12
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:39:05
User entered 'US'	System	01 Mar 2021 15:54:37

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Mar 2021 15:00:36
User entered '2'	System	09 Mar 2021 17:23:24
User entered '1'	System	01 Mar 2021 15:54:37

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:48:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:39:11
User entered '01/Mar/2021 10:54'	System	01 Mar 2021 15:54:37

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:48:20

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)	09 Apr 2021 01:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:23:12
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:39:13
User entered 'I'	(b) (4), (b) (6)	01 Mar 2021 15:54:37

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:05
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'USA-US125-2021-MRNA-1273-P301000002'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:08
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Yes (Y)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

Death

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:10
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Yes (Y)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:46
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:44
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Spyros'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Kalams'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered '1161 21st Avenue South'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Nashville'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:39:03
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered '37232'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:23:12
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:39:05
User entered 'US'	System	01 Mar 2021 15:54:37

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Mar 2021 15:00:36
User entered '2'	System	09 Mar 2021 17:23:24
User entered '1'	System	01 Mar 2021 15:54:37

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:48:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:15:51
User entered '09/Mar/2021 17:23'	System	09 Mar 2021 17:23:24

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:48:20

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)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:15:55
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 14:47:13
User entered 'I'	(b) (4), (b) (6)	09 Mar 2021 17:23:24

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:05
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'USA-US125-2021-MRNA-1273-P301000002'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:08
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Yes (Y)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:10
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:16
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Yes (Y)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:37:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:46
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'No (N)'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:44
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Spyros'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:53
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Kalams'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:55
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered '1161 21st Avenue South'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:38:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered 'Nashville'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:39:03
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:54:29
User entered '37232'	System	01 Mar 2021 15:54:11

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 17:23:12
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:39:05
User entered 'US'	System	01 Mar 2021 15:54:37

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Mar 2021 15:00:36
User entered '2'	System	09 Mar 2021 17:23:24
User entered '1'	System	01 Mar 2021 15:54:37

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:48:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:15:55
User entered '16/Mar/2021 11:00'	System	16 Mar 2021 15:00:36

US3782028

Folder: SAE USA-US125-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:48:20

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)	09 Apr 2021 01:06:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:15:55
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:00:49
Un-reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 15:00:36
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 15:00:36
Reviewed for Safety.	(b) (4), (b) (6)	16 Mar 2021 14:47:13
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 14:47:07