

US3782073 (Prod: Vanderbilt University Medical Center)

Generated By: KC Joubran

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US3782073

Form: Participant Creation

Data signed: (b) (4) 26 Jan 2021 20:14:31

Generated On: 12 Aug 2021 13:32:40

[Participant ID](#)

US3782073

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

US3782073

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3782073

Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	56
Age Units	YEARS
Age (Derived)	56
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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

US3782073

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Date of Informed Consent (dd MMM yyyy)	24 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

US3782073

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3782073

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Were any significant conditions reported?

Yes ☒

No ☐

US3782073

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Condition	SCALP PSORIASIS
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3782073

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	24 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	07:56 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 07:56
Height (<i>xxx.x</i>)	174 cm
Weight (<i>xxx.x</i>)	67.1 kg
BMI (<i>xxx.x</i>)	22.16277 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3782073

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

US3782073

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Date of assessment (dd MMM yyyy) 24 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) _____

Date of surgery unknown False

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

Date of last menstruation unknown False

US3782073

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 24 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3782073

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

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

US3782073

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

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	

US3782073

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3782073

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 106887

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 ☒

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Height	ND - Not Done
Weight	ND - Not Done

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	07:56 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 07:56
Temperature (xxx.x)	98.5 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	09:19 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 09:19
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3782073

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

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.

US3782073

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 24 AUG 2020

What was the treatment time? (00:00-23:59) 08:46 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 08:46

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

US3782073

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 AUG 2020

Collection time (00:00-23:59)

08:06 (24 HR)

Collection date and time (derived)

24 AUG 2020 08:06

US3782073

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:09	24 AUG 2020 08:09
Nasopharyngeal Swab 2	No		

US3782073

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

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

98.2 °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

24 AUG 2020 09:24

PC Open Date & Time

24 AUG 2020 09:06

PC Close Date & Time

24 AUG 2020 11:36

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	24 AUG 2020 19:22
PC Open Date & Time	24 AUG 2020 12:31
PC Close Date & Time	25 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 21:03

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:32:40

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 23:35

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 00:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 20:41

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:32:40

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	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes ☒
	No ☐

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	29 AUG 2020 22:27
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 22:48

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 09:24

PC Open Date & Time

24 AUG 2020 09:06

PC Close Date & Time

24 AUG 2020 11:36

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

5

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 19:25

PC Open Date & Time

24 AUG 2020 12:31

PC Close Date & Time

25 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

DAY 2

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

25 AUG 2020 21:04

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 23:36

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 23:59

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 20:41

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 22:25

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT	DAY 7
Please record - PAIN AT INJECTION SITE.	None ☒
Please select one response below	
Does not interfere with activity	☐
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	☐
Any use of prescription pain reliever or prevents daily activity	☐
Is there any REDNESS AT INJECTION SITE?	Yes ☐
	No ☒
Is there any SWELLING/HARDNESS AT INJECTION SITE?	Yes ☐
	No ☒
Please record - UNDERARM GLAND SWELLING OR TENDERNESS.	None ☒
Please select one response below	
Does not interfere with activity	☐
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	☐
Any use of prescription pain reliever or prevents daily activity	☐
PC Time Stamp	30 AUG 2020 22:49
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

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 ☐

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 09:25
PC Open Date & Time	24 AUG 2020 09:06
PC Close Date & Time	24 AUG 2020 11:36

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

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 ☐

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 19:26
PC Open Date & Time	24 AUG 2020 12:31
PC Close Date & Time	25 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:40

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 ☒

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:40

Yes ☐	
PC Time stamp	25 AUG 2020 21:04
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

47 of 996

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:40

Yes ☐	
PC Time stamp	26 AUG 2020 23:36
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

49 of 996

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:40

Yes ☐	
PC Time stamp	28 AUG 2020 00:00
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:40

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 ☐

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:40

		Yes ☐
PC Time stamp	28 AUG 2020 20:41	
PC Open Date & Time	28 AUG 2020 12:00	
PC Close Date & Time	29 AUG 2020 11:59	

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 996

EAB) (1725)

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:40

Yes ☐	
PC Time stamp	29 AUG 2020 22:26
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:40

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

55 of 996

EAB) (1725)

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:40

Yes ☐	
PC Time stamp	30 AUG 2020 22:50
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3782073

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782073

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 7 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3782073

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782073

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	08:01 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 08:01
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Timepoint	Pre-Dose ☐
	Post-Dose ☒
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	

US3782073

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3782073

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 21 SEP 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

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 DUE TO RECENT ANGIOEDEMA
- SEE EPIP COMMUNICATIONS

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3782073

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

08:10 (24 HR)

Collection date and time (derived)

21 SEP 2020 08:10

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:15	21 SEP 2020 08:15
Nasopharyngeal Swab 2	No		

US3782073

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782073

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782073

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782073

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	21 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒

Folder OID	VISIT3
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US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	08:30 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 08:30
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3782073

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

US3782073

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 OCT 2020

Collection time (00:00-23:59)

08:41 (24 HR)

Collection date and time (derived)

21 OCT 2020 08:41

US3782073

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:16:44

Generated On: 12 Aug 2021 13:32:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

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

24 OCT 2020 00:02:15

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

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 ☐
Have 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):	
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 ☐
Date and time of submission	03 NOV 2020 08:28:28
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

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	07 NOV 2020 00:02:19
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 09:43:52
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 02:23:48

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

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

02 DEC 2020 00:20:58

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

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

09 DEC 2020 18:37:24

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

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

17 DEC 2020 00:53:09

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 12:02:21

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3782073

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:32:40

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

US3782073

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782073

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782073

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782073

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

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

US3782073

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3782073

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:32:40

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3782073

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:32:40

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3782073

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 01:15:12

Generated On: 12 Aug 2021 13:32:40

Date of updated informed consent (dd MMM yyyy)	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	True
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)	24 DEC 2020
Participant randomization assignment	mRNA-1273 ☐ Placebo ☒
Actual Dose 1	mRNA-1273 ☐ Placebo ☒ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ☐ Not Administered ☒
Will participant receive mRNA-1273?	Yes ☐ No ☒
Placebo Only Flag	1
Continuing with mRNA-1273	

US3782073

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Jan 2021 20:14:31

Generated On: 12 Aug 2021 13:32:40

AEID

Adverse event

ANGIODEMA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

28 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

103 of 996

EAB) (1725)

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Jan 2021 20:14:31

Generated On: 12 Aug 2021 13:32:40

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	ANGIOEDEMA LOCATED ON ORAL MUCOSA, RIGHT HIP, AND BUTTOCK
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Jan 2021 20:14:31

Generated On: 12 Aug 2021 13:32:40

AEID	
Adverse event	MALAISE
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	28 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	28 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

105 of 996

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Jan 2021 20:14:31

Generated On: 12 Aug 2021 13:32:40

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ☒ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

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

Yes ☒

No ☐

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

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Name of Medication MICROGESTIN

Prophylaxis Yes ☒
No ☐

Indication CONTRACEPTION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

108 of 996

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN OCT 2010	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication ANGIOEDEMA

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)

110 of 996

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	28 AUG 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication ANGIOEDEMA

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
EAB) (1725)

112 of 996

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 28 AUG 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication ANGIOEDEMA

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
EAB) (1725)

114 of 996

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 29 AUG 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication MALAISE

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
EAB) (1725)

116 of 996

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 28 AUG 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication ANGIOEDEMA

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
EAB) (1725)

118 of 996

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 12 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Name of Medication ALLEGRA

Prophylaxis Yes ☐
No ☒

Indication ANGIOEDEMA

Dose per administration 180

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)

120 of 996

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	18 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		18 SEP 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

122 of 996

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		5 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 5 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

124 of 996

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3782073

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 23:27:52

Generated On: 12 Aug 2021 13:32:40

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3782073

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 28 Apr 2021 21:42:43

Generated On: 12 Aug 2021 13:32:40

Date of dosing discontinuation (dd MMM yyyy) 21 SEP 2020

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 AE #1

US3782073

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 26 Jan 2021 20:14:32

Generated On: 12 Aug 2021 13:32:40

Date of study discontinuation/completion (dd MMM yyyy) 24 DEC 2020

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

PARTICIPANT HAS BEEN UNBLINDED. REASON: OTHER – REQUEST TO UNBLIND / EUA COVID-19 VACCINE

If reason for discontinuation is Death, main cause of death

Adverse event	☐
Unknown	☐
Other	☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	☐
No	☐
Unknown	☐

Audit

US3782073 (Prod: Vanderbilt University Medical Center)

US3782073

Form: Participant Creation

Generated On: 12 Aug 2021 13:32:40

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'US3782073'	RWS_ENDPOINT	24 Aug 2020 12:49:34
	ENDPOINT (b) (4)	

US3782073

Form: Participant Creation

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28

US3782073

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:32:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	24 Aug 2020 12:51:21
	(b) (4)	

US3782073

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 12:49:35

US3782073

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Clinic (Clinic)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 12:51:21

US3782073

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:32:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User entered 'SCRN'	System	24 Aug 2020 12:51:21

US3782073

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:40

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered (b) (6) 1964'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 12:49:36

US3782073

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:40

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '56'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:40

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User entered 'YEARS'	System	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:40

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User entered '56'	System	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:40

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Female (F)'	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:40

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:40

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '1'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:40

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:40

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:40

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:40

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:40

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:40

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:40

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:32:40

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:38:54

US3782073

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:40

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '24 Aug 2020'	(b) (4) Carlton Griffin (b) (4)	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User entered 'Aug 2020'	System	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User entered '2020'	System	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:40

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Amendment 2 (2)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:40

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Carlton Griffin (b) (4)	24 Aug 2020 13:02:35
	(b) (4)	

US3782073

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:40

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Carlton Griffin (b) (4)	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:40

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	24 Aug 2020 13:02:35
	(b) (4)	

US3782073

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:40

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 12:49:35

US3782073

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:32:40

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User entered '1'	System	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	24 Aug 2020 12:55:54

US3782073

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:32:40

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:52:08

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Psoriatic conditions, PT: Psoriasis, LLT: Psoriasis of scalp - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Aug 2020 13:53:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 13:53:35
Data point term sent to Coder	System	24 Aug 2020 13:53:16
User entered 'scalp psoriasis'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'un UNK 1995'	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User entered 'Jan 1995'	System	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User entered '1995'	System	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User entered empty.	System	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User entered empty.	System	24 Aug 2020 13:52:39

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '24 Aug 2020'	(b) (4) Carlton Griffin (b) (4)	24 Aug 2020 13:04:46
	(b) (4)	

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '07:56'	(b) (4) Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User entered '24 Aug 2020 07:56'	System	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '174' cm	(b) (4) Carlton Griffin (b) (4)	24 Aug 2020 13:04:46
DataPoint set to visible.	(b) (4) System	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '67.1' kg	(b) (4) Carlton Griffin (b) (4)	24 Aug 2020 13:04:46
DataPoint set to visible.	(b) (4) System	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Amendment Manager: User entered '22.16277'	System	17 Sep 2020 00:20:46
User entered '22.2'	System	24 Aug 2020 13:04:46
DataPoint set to visible.	System	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User entered 'kg/m2'	System	24 Aug 2020 13:04:46
DataPoint set to visible.	System	24 Aug 2020 13:02:35

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered missing code ND - Not Done.	(b) (4) Carlton Griffin (b) (4)	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Oral (Oral)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Carlton Griffin (b) (4)	24 Aug 2020 13:04:46
	(b) (4)	

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered missing code ND - Not Done.	(b) (4) Carlton Griffin (b) (4)	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User entered 'bpm'	System	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered missing code ND - Not Done.	(b) (4) Carlton Griffin (b) (4)	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User entered 'breaths/min'	System	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered missing code ND - Not Done.	(b) (4) Carlton Griffin (b) (4)	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User entered 'mmHg'	System	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered missing code ND - Not Done.	(b) (4) Carlton Griffin (b) (4)	24 Aug 2020 13:04:46
	(b) (4)	

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User entered 'mmHg'	System	24 Aug 2020 13:04:46

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31

US3782073

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31

US3782073

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	24 Aug 2020 13:02:57

US3782073

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '24 Aug 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:02:57

US3782073

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:32:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '24 Aug 2020'	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:53:35

US3782073

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:53:35

US3782073

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:32:40

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:53:35

US3782073

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:32:40

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:53:35

US3782073

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:53:35

US3782073

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:32:40

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:53:35

US3782073

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:53:35

US3782073

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:32:40

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:53:35

US3782073

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:53:52

US3782073

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '24 Aug 2020'	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:53:52

US3782073

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Urine (URINE)'	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:53:52

US3782073

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Negative (NEGATIVE)'	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:53:52

US3782073

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:53:52

US3782073

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:53:52

US3782073

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:53:52

US3782073

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User entered empty.	System	24 Aug 2020 13:53:52

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '1'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:32:40

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:54:17

US3782073

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:32:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	24 Aug 2020 12:56:06

US3782073

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '24 Aug 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 12:56:06

US3782073

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Clinic (Clinic)'	Carlton Griffin (b) (4)	24 Aug 2020 12:56:06

US3782073

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:32:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered 'VISIT1'	System	24 Aug 2020 12:56:06

US3782073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:09
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 13:19:45

US3782073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:09
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '106887'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 13:19:45

US3782073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:09
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 13:19:45

US3782073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:40

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 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:09
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'No (N)'	Carlton Griffin (b) (4)	24 Aug 2020 13:15:54

US3782073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:40

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 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:09
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:15:54

US3782073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:09
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'No (N)'	Carlton Griffin (b) (4)	24 Aug 2020 13:15:54

US3782073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:40

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:09
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'No (N)'	Carlton Griffin (b) (4)	24 Aug 2020 13:15:54

US3782073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:40

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:09
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:15:54

US3782073

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:09
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	25 Sep 2020 18:18:08
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:39:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:24:44

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '24 Aug 2020'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '07:56'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered '24 Aug 2020 07:56'	System	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '98.5' F	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Oral (Oral)'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '64'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered 'bpm'	System	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '16'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered 'breaths/min'	System	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '124'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered 'mmHg'	System	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '75'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered 'mmHg'	System	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:40

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:32:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	24 Aug 2020 13:55:21

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	24 Aug 2020 14:28:40
	(b) (4)	

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '24 Aug 2020'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '09:19'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered '24 Aug 2020 09:19'	System	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '98.2' F	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Oral (Oral)'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '60'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered 'bpm'	System	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '16'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered 'breaths/min'	System	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '132'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered 'mmHg'	System	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '84'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:40:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered 'mmHg'	System	24 Aug 2020 14:28:40

US3782073

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:02
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'No (N)'	Carlton Griffin (b) (4)	24 Aug 2020 13:21:09

US3782073

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:02
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	Carlton Griffin (b) (4)	24 Aug 2020 13:21:09

US3782073

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:09
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:54

US3782073

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:09
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:54

US3782073

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:09
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:54

US3782073

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:09
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:54

US3782073

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:09
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User closed query 'per CDM: please select yes or no for this field' (Site from DM).	(b) (4)	
Query 'per CDM: please select yes or no for this field' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 22:15:56
User entered 'No (N)' reason for change: Data Entry Error	Carlton Griffin (b) (4)	04 Nov 2020 19:29:33
User opened query 'per CDM: please select yes or no for this field' (Site from DM).	(b) (4)	
User entered empty.	Amber Massey (b) (4)	04 Nov 2020 19:29:27
	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:24:26
	(b) (4)	
	Amber Massey (b) (4)	24 Aug 2020 13:55:54
	(b) (4)	

US3782073

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:09
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:54

US3782073

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:09
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:55:54

US3782073

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:09
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered empty.	System	24 Aug 2020 13:55:54

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:17
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:17
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:17
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:17
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:17
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '24 Aug 2020'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:17
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '08:46'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:17
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered '24 Aug 2020 08:46'	System	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:17
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Left Arm (LEFT ARM)'	(b) (4) Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:17
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered 'ONCE'	System	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:17
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 13:56:20

US3782073

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	24 Aug 2020 13:21:30
	(b) (4)	

US3782073

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '24 Aug 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:21:30

US3782073

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '08:06'	(b) (4) Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:21:30

US3782073

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered '24 Aug 2020 08:06'	System	24 Aug 2020 13:21:30

US3782073

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:32:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:35
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '24 Aug 2020'	Carlton Griffin (b) (4)	24 Aug 2020 13:21:51

US3782073

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:32:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:35
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:21:51

US3782073

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:32:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:35
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	24 Aug 2020 13:21:51

US3782073

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:32:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:35
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '08:09'	Carlton Griffin (b) (4)	24 Aug 2020 13:21:51

US3782073

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:32:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:35
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered '24 Aug 2020 08:09'	System	24 Aug 2020 13:21:51

US3782073

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:32:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:35
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Carlton Griffin (b) (4) (b) (4)	24 Aug 2020 13:21:51

US3782073

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:32:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:35
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	Carlton Griffin (b) (4)	24 Aug 2020 13:21:51

US3782073

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:32:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:35
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	Carlton Griffin (b) (4)	24 Aug 2020 13:21:51

US3782073

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:32:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:35
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered empty.	System	24 Aug 2020 13:21:51

US3782073

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:48
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	24 Aug 2020 13:21:14

US3782073

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:41:48
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered '1'	System	24 Aug 2020 13:21:14

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:23:42', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '3824708b-003b-4ec8-b5de-91a1e56477b3' User entered 'Yes (Y)'	System	24 Aug 2020 14:24:04
	System	24 Aug 2020 14:24:04

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:23:51', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '3824708b-003b-4ec8-b5de-91a1e56477b3' User entered '98.2'	System	24 Aug 2020 14:24:04
	System	24 Aug 2020 14:24:04

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:23:56', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '3824708b-003b-4ec8-b5de-91a1e56477b3'	System	24 Aug 2020 14:24:04
User entered 'No (N)'	System	24 Aug 2020 14:24:04

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:24:02', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '3824708b-003b-4ec8-b5de-91a1e56477b3' User entered '24 Aug 2020 09:24'	System	24 Aug 2020 14:24:04
	System	24 Aug 2020 14:24:04

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '24 Aug 2020 09:06'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '24 Aug 2020 11:36'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:22:22', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '23f6220a-f26f-4749-b780-693a1efe8821' User entered 'Yes (Y)'	System	25 Aug 2020 00:22:41
	System	25 Aug 2020 00:22:41

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:22:28', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '23f6220a-f26f-4749-b780-693a1efe8821' User entered '97.5'	System	25 Aug 2020 00:22:41
	System	25 Aug 2020 00:22:41

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:22:34', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '23f6220a-f26f-4749-b780-693a1efe8821'	System	25 Aug 2020 00:22:41
User entered 'No (N)'	System	25 Aug 2020 00:22:41

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:22:39', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '23f6220a-f26f-4749-b780-693a1efe8821' User entered '24 Aug 2020 19:22'	System	25 Aug 2020 00:22:41
	System	25 Aug 2020 00:22:41

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '24 Aug 2020 12:31'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 2'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:32:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:03:29', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '4be7c488-5552-4380-ac93-f1fc53f17f27'	System	26 Aug 2020 02:03:43
User entered 'Yes (Y)'	System	26 Aug 2020 02:03:43

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:32:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:03:33', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '4be7c488-5552-4380-ac93-f1fc53f17f27' User entered '97.4'	System	26 Aug 2020 02:03:43
	System	26 Aug 2020 02:03:43

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:03:37', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '4be7c488-5552-4380-ac93-f1fc53f17f27'	System	26 Aug 2020 02:03:43
User entered 'No (N)'	System	26 Aug 2020 02:03:43

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:03:40', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '4be7c488-5552-4380-ac93-f1fc53f17f27'	System	26 Aug 2020 02:03:43
User entered '25 Aug 2020 21:03'	System	26 Aug 2020 02:03:43

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 3'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:32:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:34:58', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'f27c54e8-0099-4c28-8cbe-71335dc17f40' User entered 'Yes (Y)'	System	27 Aug 2020 04:35:24
	System	27 Aug 2020 04:35:24

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:32:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:35:14', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'f27c54e8-0099-4c28-8cbe-71335dc17f40' User entered '96.8'	System	27 Aug 2020 04:35:24
	System	27 Aug 2020 04:35:24

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:35:19', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'f27c54e8-0099-4c28-8cbe-71335dc17f40'	System	27 Aug 2020 04:35:24
User entered 'No (N)'	System	27 Aug 2020 04:35:24

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:35:21', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'f27c54e8-0099-4c28-8cbe-71335dc17f40'	System	27 Aug 2020 04:35:24
User entered '26 Aug 2020 23:35'	System	27 Aug 2020 04:35:24

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 4'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:32:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:45', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '4b54dbdd-7d85-4d1b-92fd-2752c2bb6f62'	System	28 Aug 2020 05:00:59
User entered 'Yes (Y)'	System	28 Aug 2020 05:00:59

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:32:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:50', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '4b54dbdd-7d85-4d1b-92fd-2752c2bb6f62' User entered '97.9'	System	28 Aug 2020 05:00:59
	System	28 Aug 2020 05:00:59

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:54', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '4b54dbdd-7d85-4d1b-92fd-2752c2bb6f62'	System	28 Aug 2020 05:00:59
User entered 'No (N)'	System	28 Aug 2020 05:00:59

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:57', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '4b54dbdd-7d85-4d1b-92fd-2752c2bb6f62'	System	28 Aug 2020 05:00:59
User entered '28 Aug 2020 00:00'	System	28 Aug 2020 05:00:59

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 5'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:32:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:40:48', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '2b85e4e8-973f-4db3-89ec-2fccda98c5c7'	System	29 Aug 2020 01:41:15
User entered 'Yes (Y)'	System	29 Aug 2020 01:41:15

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:32:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:40:58', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '2b85e4e8-973f-4db3-89ec-2fccda98c5c7' User entered '97.0'	System	29 Aug 2020 01:41:15
	System	29 Aug 2020 01:41:15

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:08', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '2b85e4e8-973f-4db3-89ec-2fccda98c5c7'	System	29 Aug 2020 01:41:15
User entered 'No (N)'	System	29 Aug 2020 01:41:15

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:12', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '2b85e4e8-973f-4db3-89ec-2fccda98c5c7'	System	29 Aug 2020 01:41:15
User entered '28 Aug 2020 20:41'	System	29 Aug 2020 01:41:15

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 6'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:32:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:26:34', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '835d4735-656a-4033-9966-717dbaa676f4'	System	30 Aug 2020 03:27:21
User entered 'Yes (Y)'	System	30 Aug 2020 03:27:21

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:32:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:26:38', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '835d4735-656a-4033-9966-717dbaa676f4' User entered '97.5'	System	30 Aug 2020 03:27:21
	System	30 Aug 2020 03:27:21

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:26:59', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '835d4735-656a-4033-9966-717dbaa676f4'	System	30 Aug 2020 03:27:21
User entered 'Yes (Y)'	System	30 Aug 2020 03:27:21

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed and documented' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 15:14:08
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:27:13', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '835d4735-656a-4033-9966-717dbaa676f4' User entered '1'	System	30 Aug 2020 03:27:21
	System	30 Aug 2020 03:27:21
	System	30 Aug 2020 03:27:21

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:32:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:27:13', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '835d4735-656a-4033-9966-717dbaa676f4' User entered '0'	System	30 Aug 2020 03:27:21
	System	30 Aug 2020 03:27:21

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:27:18', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '835d4735-656a-4033-9966-717dbaa676f4' User entered '29 Aug 2020 22:27'	System	30 Aug 2020 03:27:21
	System	30 Aug 2020 03:27:21

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 7'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:32:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:48:30', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9abbae47-acc6-41ed-b2f2-967ec0986753' User entered 'Yes (Y)'	System	31 Aug 2020 03:48:44
	System	31 Aug 2020 03:48:44

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:32:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:48:35', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9abbae47-acc6-41ed-b2f2-967ec0986753' User entered '98.6'	System	31 Aug 2020 03:48:44
	System	31 Aug 2020 03:48:44

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:48:37', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9abbae47-acc6-41ed-b2f2-967ec0986753' User entered 'No (N)'	System	31 Aug 2020 03:48:44
	System	31 Aug 2020 03:48:44

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:48:42', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9abbae47-acc6-41ed-b2f2-967ec0986753' User entered '30 Aug 2020 22:48'	System	31 Aug 2020 03:48:44
	System	31 Aug 2020 03:48:44

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:24:18', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'a9f22876-e725-4909-94e4-c5569db0b820'	System	24 Aug 2020 14:24:47
User entered 'None (1)'	System	24 Aug 2020 14:24:47

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:24:23', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'a9f22876-e725-4909-94e4-c5569db0b820' User entered 'No (N)'	System	24 Aug 2020 14:24:47
	System	24 Aug 2020 14:24:47

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:24:28', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'a9f22876-e725-4909-94e4-c5569db0b820'	System	24 Aug 2020 14:24:47
User entered 'No (N)'	System	24 Aug 2020 14:24:47

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:24:38', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'a9f22876-e725-4909-94e4-c5569db0b820'	System	24 Aug 2020 14:24:47
User entered 'None (1)'	System	24 Aug 2020 14:24:47

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:24:44', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'a9f22876-e725-4909-94e4-c5569db0b820' User entered '24 Aug 2020 09:24'	System	24 Aug 2020 14:24:47
	System	24 Aug 2020 14:24:47

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '24 Aug 2020 09:06'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '24 Aug 2020 11:36'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:22:58', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'abcad6eb-ffb0-433e-a235-197633652953'	System	25 Aug 2020 00:25:36
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 00:25:36

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:23:02', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'abcd6eb-ffb0-433e-a235-197633652953' User entered 'No (N)'	System	25 Aug 2020 00:25:36
	System	25 Aug 2020 00:25:36

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:23:07', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'abcad6eb-ffb0-433e-a235-197633652953' User entered 'Yes (Y)'	System	25 Aug 2020 00:25:36
	System	25 Aug 2020 00:25:36

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:25:14', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'abcad6eb-ffb0-433e-a235-197633652953' User entered '5'	System	25 Aug 2020 00:25:36
	System	25 Aug 2020 00:25:36

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:25:27', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'abcd6eb-ffb0-433e-a235-197633652953' User entered 'None (1)'	System	25 Aug 2020 00:25:36
	System	25 Aug 2020 00:25:36

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:25:34', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'abcd6eb-ffb0-433e-a235-197633652953' User entered '24 Aug 2020 19:25'	System	25 Aug 2020 00:25:36
	System	25 Aug 2020 00:25:36

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '24 Aug 2020 12:31'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 2'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:03:46', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '941b796b-f9cb-437a-88db-3d36b124365e' User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 02:04:19
	System	26 Aug 2020 02:04:19

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:03:49', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '941b796b-f9cb-437a-88db-3d36b124365e' User entered 'No (N)'	System	26 Aug 2020 02:04:19
	System	26 Aug 2020 02:04:19

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:02', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '941b796b-f9cb-437a-88db-3d36b124365e' User entered 'No (N)'	System	26 Aug 2020 02:04:19
	System	26 Aug 2020 02:04:19

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:08', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '941b796b-f9cb-437a-88db-3d36b124365e' User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 02:04:19
	System	26 Aug 2020 02:04:19

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:13', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '941b796b-f9cb-437a-88db-3d36b124365e' User entered '25 Aug 2020 21:04'	System	26 Aug 2020 02:04:19
	System	26 Aug 2020 02:04:19

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 3'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:35:32', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd26e7c6f-ec53-427f-a1d5-ce02818a8308'	System	27 Aug 2020 04:36:24
User entered 'None (1)'	System	27 Aug 2020 04:36:24

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:35:35', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd26e7c6f-ec53-427f-a1d5-ce02818a8308' User entered 'No (N)'	System	27 Aug 2020 04:36:24
	System	27 Aug 2020 04:36:24

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:35:38', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd26e7c6f-ec53-427f-a1d5-ce02818a8308'	System	27 Aug 2020 04:36:24
User entered 'No (N)'	System	27 Aug 2020 04:36:24

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:18', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd26e7c6f-ec53-427f-a1d5-ce02818a8308'	System	27 Aug 2020 04:36:24
User entered 'None (1)'	System	27 Aug 2020 04:36:24

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:21', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd26e7c6f-ec53-427f-a1d5-ce02818a8308' User entered '26 Aug 2020 23:36'	System	27 Aug 2020 04:36:24
	System	27 Aug 2020 04:36:24

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 4'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-27T23:59:44', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '29d8a3d6-d699-418e-b306-4a18540ebe5f' User entered 'None (1)'	System	28 Aug 2020 05:00:05
	System	28 Aug 2020 05:00:05

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:32:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-27T23:59:47', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '29d8a3d6-d699-418e-b306-4a18540ebe5f' User entered 'No (N)'	System	28 Aug 2020 05:00:05
	System	28 Aug 2020 05:00:05

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-27T23:59:50', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '29d8a3d6-d699-418e-b306-4a18540ebe5f' User entered 'No (N)'	System	28 Aug 2020 05:00:05
	System	28 Aug 2020 05:00:05

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-27T23:59:54', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '29d8a3d6-d699-418e-b306-4a18540ebe5f' User entered 'None (1)'	System	28 Aug 2020 05:00:05
	System	28 Aug 2020 05:00:05

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-27T23:59:58', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '29d8a3d6-d699-418e-b306-4a18540ebe5f' User entered '27 Aug 2020 23:59'	System	28 Aug 2020 05:00:05
	System	28 Aug 2020 05:00:05

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 5'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:15', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '17fb1143-7c06-457b-9b26-19cae8dad8a0'	System	29 Aug 2020 01:41:33
User entered 'None (1)'	System	29 Aug 2020 01:41:33

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:32:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:19', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '17fb1143-7c06-457b-9b26-19cae8dad8a0' User entered 'No (N)'	System	29 Aug 2020 01:41:33
	System	29 Aug 2020 01:41:33

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:22', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '17fb1143-7c06-457b-9b26-19cae8dad8a0' User entered 'No (N)'	System	29 Aug 2020 01:41:33
	System	29 Aug 2020 01:41:33

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:29', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '17fb1143-7c06-457b-9b26-19cae8dad8a0'	System	29 Aug 2020 01:41:33
User entered 'None (1)'	System	29 Aug 2020 01:41:33

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:31', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '17fb1143-7c06-457b-9b26-19cae8dad8a0' User entered '28 Aug 2020 20:41'	System	29 Aug 2020 01:41:33
	System	29 Aug 2020 01:41:33

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 6'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:25:27', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'fdfcbe7f-eca3-4902-834b-e3220b135012'	System	30 Aug 2020 03:25:45
User entered 'None (1)'	System	30 Aug 2020 03:25:45

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:32:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:25:30', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'fdfcbe7f-eca3-4902-834b-e3220b135012'	System	30 Aug 2020 03:25:45
User entered 'No (N)'	System	30 Aug 2020 03:25:45

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:25:33', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'fdfcbe7f-eca3-4902-834b-e3220b135012'	System	30 Aug 2020 03:25:45
User entered 'No (N)'	System	30 Aug 2020 03:25:45

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:25:40', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'fdfcbe7f-eca3-4902-834b-e3220b135012'	System	30 Aug 2020 03:25:45
User entered 'None (1)'	System	30 Aug 2020 03:25:45

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:25:43', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'fdfcbe7f-eca3-4902-834b-e3220b135012'	System	30 Aug 2020 03:25:45
User entered '29 Aug 2020 22:25'	System	30 Aug 2020 03:25:45

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 7'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:48:46', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9919d471-7c8a-4925-aa2c-adcf30986273' User entered 'None (1)'	System	31 Aug 2020 03:49:09
	System	31 Aug 2020 03:49:09

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:32:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:48:49', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9919d471-7c8a-4925-aa2c-adcf30986273' User entered 'No (N)'	System	31 Aug 2020 03:49:09
	System	31 Aug 2020 03:49:09

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:48:52', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9919d471-7c8a-4925-aa2c-adcf30986273' User entered 'No (N)'	System	31 Aug 2020 03:49:09
	System	31 Aug 2020 03:49:09

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:48:58', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9919d471-7c8a-4925-aa2c-adcf30986273'	System	31 Aug 2020 03:49:09
User entered 'None (1)'	System	31 Aug 2020 03:49:09

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:49:07', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9919d471-7c8a-4925-aa2c-adcf30986273' User entered '30 Aug 2020 22:49'	System	31 Aug 2020 03:49:09
	System	31 Aug 2020 03:49:09

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:24:53', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9e051fe8-8afc-400c-a0e9-afecdc593d9a' User entered 'None (0)'	System	24 Aug 2020 14:25:28
	System	24 Aug 2020 14:25:28

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:25:00', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9e051fe8-8afc-400c-a0e9-afecdc593d9a'	System	24 Aug 2020 14:25:28
User entered 'None (0)'	System	24 Aug 2020 14:25:28

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:25:03', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9e051fe8-8afc-400c-a0e9-afecdc593d9a' User entered 'None (0)'	System	24 Aug 2020 14:25:28
	System	24 Aug 2020 14:25:28

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:25:07', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9e051fe8-8afc-400c-a0e9-afecdc593d9a' User entered 'None (0)'	System	24 Aug 2020 14:25:28
	System	24 Aug 2020 14:25:28

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:25:09', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9e051fe8-8afc-400c-a0e9-afecdc593d9a' User entered 'None (0)'	System	24 Aug 2020 14:25:28
	System	24 Aug 2020 14:25:28

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:25:11', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9e051fe8-8afc-400c-a0e9-afecdc593d9a'	System	24 Aug 2020 14:25:28
User entered 'None (0)'	System	24 Aug 2020 14:25:28

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:25:16', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9e051fe8-8afc-400c-a0e9-afecdc593d9a' User entered 'No (N)'	System	24 Aug 2020 14:25:28
	System	24 Aug 2020 14:25:28

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T09:25:24', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '9e051fe8-8afc-400c-a0e9-afecdc593d9a' User entered '24 Aug 2020 09:25'	System	24 Aug 2020 14:25:28
	System	24 Aug 2020 14:25:28

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '24 Aug 2020 09:06'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '24 Aug 2020 11:36'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:26:09', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '20c45288-fb6c-4a7b-9ff7-9a44596339ec' User entered 'None (0)'	System	25 Aug 2020 00:26:47
	System	25 Aug 2020 00:26:47

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:26:14', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '20c45288-fb6c-4a7b-9ff7-9a44596339ec' User entered 'None (0)'	System	25 Aug 2020 00:26:47
	System	25 Aug 2020 00:26:47

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:26:22', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '20c45288-fb6c-4a7b-9ff7-9a44596339ec' User entered 'None (0)'	System	25 Aug 2020 00:26:47
	System	25 Aug 2020 00:26:47

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:26:29', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '20c45288-fb6c-4a7b-9ff7-9a44596339ec' User entered 'None (0)'	System	25 Aug 2020 00:26:47
	System	25 Aug 2020 00:26:47

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:26:31', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '20c45288-fb6c-4a7b-9ff7-9a44596339ec' User entered 'None (0)'	System	25 Aug 2020 00:26:47
	System	25 Aug 2020 00:26:47

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:26:33', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '20c45288-fb6c-4a7b-9ff7-9a44596339ec' User entered 'None (0)'	System	25 Aug 2020 00:26:47
	System	25 Aug 2020 00:26:47

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:26:41', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '20c45288-fb6c-4a7b-9ff7-9a44596339ec' User entered 'No (N)'	System	25 Aug 2020 00:26:47
	System	25 Aug 2020 00:26:47

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-24T19:26:45', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '20c45288-fb6c-4a7b-9ff7-9a44596339ec' User entered '24 Aug 2020 19:26'	System	25 Aug 2020 00:26:47
	System	25 Aug 2020 00:26:47

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '24 Aug 2020 12:31'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 2'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:20', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd85cdd69-69ff-460a-ae91-4ecd1885b20a'	System	26 Aug 2020 02:04:53
User entered 'No interference with activity (1)'	System	26 Aug 2020 02:04:53

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:26', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd85cdd69-69ff-460a-ae91-4ecd1885b20a' User entered 'None (0)'	System	26 Aug 2020 02:04:53
	System	26 Aug 2020 02:04:53

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:28', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd85cdd69-69ff-460a-ae91-4ecd1885b20a' User entered 'None (0)'	System	26 Aug 2020 02:04:53
	System	26 Aug 2020 02:04:53

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:30', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd85cdd69-69ff-460a-ae91-4ecd1885b20a' User entered 'None (0)'	System	26 Aug 2020 02:04:53
	System	26 Aug 2020 02:04:53

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:32', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd85cdd69-69ff-460a-ae91-4ecd1885b20a' User entered 'None (0)'	System	26 Aug 2020 02:04:53
	System	26 Aug 2020 02:04:53

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:34', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd85cdd69-69ff-460a-ae91-4ecd1885b20a' User entered 'None (0)'	System	26 Aug 2020 02:04:53
	System	26 Aug 2020 02:04:53

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:41', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd85cdd69-69ff-460a-ae91-4ecd1885b20a' User entered 'No (N)'	System	26 Aug 2020 02:04:53
	System	26 Aug 2020 02:04:53

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-25T21:04:45', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd85cdd69-69ff-460a-ae91-4ecd1885b20a' User entered '25 Aug 2020 21:04'	System	26 Aug 2020 02:04:53
	System	26 Aug 2020 02:04:53

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 3'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:27', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '93cef052-9cb9-4236-980b-8a35072f564f'	System	27 Aug 2020 04:36:57
User entered 'No interference with activity (1)'	System	27 Aug 2020 04:36:57

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:30', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '93cef052-9cb9-4236-980b-8a35072f564f'	System	27 Aug 2020 04:36:57
User entered 'No interference with activity (1)'	System	27 Aug 2020 04:36:57

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:40', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '93cef052-9cb9-4236-980b-8a35072f564f' User entered 'None (0)'	System	27 Aug 2020 04:36:57
	System	27 Aug 2020 04:36:57

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:43', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '93cef052-9cb9-4236-980b-8a35072f564f'	System	27 Aug 2020 04:36:57
User entered 'No interference with activity (1)'	System	27 Aug 2020 04:36:57

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:46', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '93cef052-9cb9-4236-980b-8a35072f564f' User entered 'None (0)'	System	27 Aug 2020 04:36:57
	System	27 Aug 2020 04:36:57

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:49', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '93cef052-9cb9-4236-980b-8a35072f564f' User entered 'None (0)'	System	27 Aug 2020 04:36:57
	System	27 Aug 2020 04:36:57

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:52', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '93cef052-9cb9-4236-980b-8a35072f564f' User entered 'No (N)'	System	27 Aug 2020 04:36:57
	System	27 Aug 2020 04:36:57

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-26T23:36:55', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '93cef052-9cb9-4236-980b-8a35072f564f' User entered '26 Aug 2020 23:36'	System	27 Aug 2020 04:36:57
	System	27 Aug 2020 04:36:57

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 4'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:03', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'bd0dbf80-084a-4f18-9a93-592921abf513' User entered 'None (0)'	System	28 Aug 2020 05:00:35
	System	28 Aug 2020 05:00:35

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:29', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'bd0dbf80-084a-4f18-9a93-592921abf513' User entered 'None (0)'	System	28 Aug 2020 05:00:35
	System	28 Aug 2020 05:00:35

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:11', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'bd0dbf80-084a-4f18-9a93-592921abf513' User entered 'None (0)'	System	28 Aug 2020 05:00:35
	System	28 Aug 2020 05:00:35

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:16', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'bd0dbf80-084a-4f18-9a93-592921abf513' User entered 'None (0)'	System	28 Aug 2020 05:00:35
	System	28 Aug 2020 05:00:35

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:18', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'bd0dbf80-084a-4f18-9a93-592921abf513' User entered 'None (0)'	System	28 Aug 2020 05:00:35
	System	28 Aug 2020 05:00:35

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:22', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'bd0dbf80-084a-4f18-9a93-592921abf513' User entered 'None (0)'	System	28 Aug 2020 05:00:35
	System	28 Aug 2020 05:00:35

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:26', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'bd0dbf80-084a-4f18-9a93-592921abf513' User entered 'No (N)'	System	28 Aug 2020 05:00:35
	System	28 Aug 2020 05:00:35

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T00:00:32', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'bd0dbf80-084a-4f18-9a93-592921abf513' User entered '28 Aug 2020 00:00'	System	28 Aug 2020 05:00:35
	System	28 Aug 2020 05:00:35

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 5'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:37', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6a5d8a16-6421-4427-aa78-363e3c0c25ff' User entered 'None (0)'	System	29 Aug 2020 01:42:01
	System	29 Aug 2020 01:42:01

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:40', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6a5d8a16-6421-4427-aa78-363e3c0c25ff' User entered 'None (0)'	System	29 Aug 2020 01:42:01
	System	29 Aug 2020 01:42:01

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:43', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6a5d8a16-6421-4427-aa78-363e3c0c25ff' User entered 'None (0)'	System	29 Aug 2020 01:42:01
	System	29 Aug 2020 01:42:01

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:45', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6a5d8a16-6421-4427-aa78-363e3c0c25ff' User entered 'None (0)'	System	29 Aug 2020 01:42:01
	System	29 Aug 2020 01:42:01

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:47', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6a5d8a16-6421-4427-aa78-363e3c0c25ff' User entered 'None (0)'	System	29 Aug 2020 01:42:01
	System	29 Aug 2020 01:42:01

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:49', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6a5d8a16-6421-4427-aa78-363e3c0c25ff' User entered 'None (0)'	System	29 Aug 2020 01:42:01
	System	29 Aug 2020 01:42:01

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:57', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6a5d8a16-6421-4427-aa78-363e3c0c25ff' User entered 'Yes (Y)'	System	29 Aug 2020 01:42:01
	System	29 Aug 2020 01:42:01

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-28T20:41:59', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6a5d8a16-6421-4427-aa78-363e3c0c25ff' User entered '28 Aug 2020 20:41'	System	29 Aug 2020 01:42:01
	System	29 Aug 2020 01:42:01

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 6'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:25:57', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'ba88fe17-acec-4d1b-9fba-d6a8196105ee' User entered 'None (0)'	System	30 Aug 2020 03:26:31
	System	30 Aug 2020 03:26:31

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:25:59', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'ba88fe17-acec-4d1b-9fba-d6a8196105ee' User entered 'None (0)'	System	30 Aug 2020 03:26:31
	System	30 Aug 2020 03:26:31

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:26:02', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'ba88fe17-acec-4d1b-9fba-d6a8196105ee' User entered 'None (0)'	System	30 Aug 2020 03:26:31
	System	30 Aug 2020 03:26:31

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:26:05', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'ba88fe17-acec-4d1b-9fba-d6a8196105ee' User entered 'None (0)'	System	30 Aug 2020 03:26:31
	System	30 Aug 2020 03:26:31

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:26:08', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'ba88fe17-acec-4d1b-9fba-d6a8196105ee' User entered 'None (0)'	System	30 Aug 2020 03:26:31
	System	30 Aug 2020 03:26:31

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:26:10', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'ba88fe17-acec-4d1b-9fba-d6a8196105ee' User entered 'None (0)'	System	30 Aug 2020 03:26:31
	System	30 Aug 2020 03:26:31

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:26:27', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'ba88fe17-acec-4d1b-9fba-d6a8196105ee' User entered 'No (N)'	System	30 Aug 2020 03:26:31
	System	30 Aug 2020 03:26:31

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-29T22:26:29', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'ba88fe17-acec-4d1b-9fba-d6a8196105ee' User entered '29 Aug 2020 22:26'	System	30 Aug 2020 03:26:31
	System	30 Aug 2020 03:26:31

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 7'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:40

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:49:11', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e802c222-89fa-4367-b160-0128f05a7b34' User entered 'None (0)'	System	31 Aug 2020 03:50:26
	System	31 Aug 2020 03:50:26

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:40

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:49:16', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e802c222-89fa-4367-b160-0128f05a7b34' User entered 'None (0)'	System	31 Aug 2020 03:50:26
	System	31 Aug 2020 03:50:26

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:49:18', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e802c222-89fa-4367-b160-0128f05a7b34' User entered 'None (0)'	System	31 Aug 2020 03:50:26
	System	31 Aug 2020 03:50:26

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:49:20', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e802c222-89fa-4367-b160-0128f05a7b34' User entered 'None (0)'	System	31 Aug 2020 03:50:26
	System	31 Aug 2020 03:50:26

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:49:54', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e802c222-89fa-4367-b160-0128f05a7b34' User entered 'None (0)'	System	31 Aug 2020 03:50:26
	System	31 Aug 2020 03:50:26

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:40

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:50:00', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e802c222-89fa-4367-b160-0128f05a7b34' User entered 'None (0)'	System	31 Aug 2020 03:50:26
	System	31 Aug 2020 03:50:26

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:40

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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:50:09', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e802c222-89fa-4367-b160-0128f05a7b34' User entered 'No (N)'	System	31 Aug 2020 03:50:26
	System	31 Aug 2020 03:50:26

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:40

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-08-30T22:50:24', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e802c222-89fa-4367-b160-0128f05a7b34' User entered '30 Aug 2020 22:50'	System	31 Aug 2020 03:50:26
	System	31 Aug 2020 03:50:26

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 13:56:20

US3782073

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:39:41
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 14:06:16

US3782073

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:39:41
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 14:06:16

US3782073

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:39:41
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 14:06:16

US3782073

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:39:41
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 14:06:16

US3782073

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:39:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 14:06:22

US3782073

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:39:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered '1'	System	31 Aug 2020 14:06:22

US3782073

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:39:27
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:57:00

US3782073

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:39:27
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '7 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:57:00

US3782073

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:39:27
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:57:00

US3782073

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:39:27
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:57:00

US3782073

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:39:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 16:57:08

US3782073

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 16:39:32
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:30:36
User entered '1'	System	08 Sep 2020 16:57:08

US3782073

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	14 Sep 2020 13:04:25

US3782073

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '14 Sep 2020'	(b) (4) Carlton Griffin (b) (4)	14 Sep 2020 13:04:25

US3782073

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	14 Sep 2020 13:04:25

US3782073

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Carlton Griffin (b) (4)	14 Sep 2020 13:04:25
	(b) (4)	

US3782073

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	14 Sep 2020 13:04:31

US3782073

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:49:31
User entered '1'	System	14 Sep 2020 13:04:31

US3782073

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 21:55:24

US3782073

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 21:55:24

US3782073

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 21:55:24

US3782073

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered 'VISIT2'	System	21 Sep 2020 21:55:24

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '08:01'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered '21 Sep 2020 08:01'	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '59'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered 'bpm'	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '16'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered 'breaths/min'	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '124'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered 'mmHg'	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '72'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:32:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered 'mmHg'	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4) System	27 Oct 2020 16:32:26
Comment added 'did not receive 2nd dose, so no post-vaccine VS done'.	(b) (4), (b) (6)	17 Oct 2020 16:07:14
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	15 Oct 2020 16:28:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered empty.	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty; reason for change Per Query Resolution	Carlton Griffin (b) (4)	27 Oct 2020 16:32:26
User closed query 'per CDM: please use drop down menu to enter ND for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP if vitals were not taken' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:04:55
Query 'per CDM: please use drop down menu to enter ND for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP if vitals were not taken' answered with 'updated- query still showing up that vital signs were not assessed but data is provided. is this correct?' (Site from DM).	Carlton Griffin (b) (4)	15 Oct 2020 16:29:20
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carlton Griffin (b) (4)	15 Oct 2020 16:28:46
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carlton Griffin (b) (4)	15 Oct 2020 16:28:34
User opened query 'per CDM: please use drop down menu to enter ND for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP if vitals were not taken' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 16:12:57
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty; reason for change Per Query Resolution	Carlton Griffin (b) (4)	27 Oct 2020 16:32:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carlton Griffin (b) (4)	15 Oct 2020 16:28:34
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered empty.	System	27 Oct 2020 16:32:26
User entered 'bpm'	System	15 Oct 2020 16:28:34
User entered empty.	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty; reason for change Per Query Resolution	Carlton Griffin (b) (4)	27 Oct 2020 16:32:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carlton Griffin (b) (4)	15 Oct 2020 16:28:34
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered empty.	System	27 Oct 2020 16:32:26
User entered 'breaths/min'	System	15 Oct 2020 16:28:34
User entered empty.	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty; reason for change Per Query Resolution	(b) (4) Carlton Griffin (b) (4)	27 Oct 2020 16:32:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4) Carlton Griffin (b) (4)	15 Oct 2020 16:28:34
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered empty.	System	27 Oct 2020 16:32:26
User entered 'mmHg'	System	15 Oct 2020 16:28:34
User entered empty.	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty; reason for change Per Query Resolution	Carlton Griffin (b) (4)	27 Oct 2020 16:32:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	Carlton Griffin (b) (4)	15 Oct 2020 16:28:34
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:32:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered empty.	System	27 Oct 2020 16:32:26
User entered 'mmHg'	System	15 Oct 2020 16:28:34
User entered empty.	System	21 Sep 2020 22:12:51

US3782073

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 21:58:43

US3782073

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 21:58:43

US3782073

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:00:34

US3782073

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:00:34

US3782073

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:00:34

US3782073

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:00:34

US3782073

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:00:34

US3782073

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:00:34

US3782073

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:00:34

US3782073

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:32:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered empty.	System	21 Sep 2020 22:00:34

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Physician Decision (PHYSICIAN DECISION)' reason for change: New Information	(b) (4)	22 Sep 2020 20:38:09
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4), (b) (6)	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Due to recent angioedema - see ePip communications'	(b) (4), (b) (6)	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered empty.	System	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered empty.	System	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered empty.	System	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:32:40

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered empty.	System	21 Sep 2020 21:55:01

US3782073

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 21:59:46

US3782073

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 21:59:46

US3782073

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '08:10'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 21:59:46

US3782073

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered '21 Sep 2020 08:10'	System	21 Sep 2020 21:59:46

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:32:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:00:09

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:32:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Sep 2020 22:00:09

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:32:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:00:09

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:32:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '08:15'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:00:09

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:32:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered '21 Sep 2020 08:15'	System	21 Sep 2020 22:00:09

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:32:40

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Sep 2020 22:00:09

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:32:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:00:09

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:32:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:00:09

US3782073

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:32:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered empty.	System	21 Sep 2020 22:00:09

US3782073

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:13:02

US3782073

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:18:14
User entered '1'	System	21 Sep 2020 22:13:02

US3782073

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:28:08
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	29 Sep 2020 13:00:17

US3782073

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:28:08
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	14 Dec 2020 14:25:58
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 14:19:42
User entered '29 Sep 2020'	Carlton Griffin (b) (4)	29 Sep 2020 13:00:17
	(b) (4)	

US3782073

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:28:08
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	29 Sep 2020 13:00:17

US3782073

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:28:08
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Carlton Griffin (b) (4)	29 Sep 2020 13:00:17

US3782073

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:28:08
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	29 Sep 2020 13:00:25

US3782073

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:28:08
User entered '1'	System	29 Sep 2020 13:00:25

US3782073

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 14:42:55

US3782073

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 14:25:58
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 14:19:42
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 14:42:55

US3782073

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 14:42:55

US3782073

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 14:42:55

US3782073

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 14:43:01

US3782073

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:24:58
User entered '1'	System	05 Oct 2020 14:43:01

US3782073

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:30:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'Yes (Y)'	Amy Kerrigan (b) (4)	12 Oct 2020 16:41:45
	(b) (4)	

US3782073

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:30:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 14:25:58
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 14:19:42
User entered '12 Oct 2020'	Amy Kerrigan (b) (4)	12 Oct 2020 16:41:45
	(b) (4)	

US3782073

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:30:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Amy Kerrigan (b) (4)	12 Oct 2020 16:41:45
	(b) (4)	

US3782073

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:30:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered empty.	Amy Kerrigan (b) (4)	12 Oct 2020 16:41:45
	(b) (4)	

US3782073

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:30:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'Yes (Y)'	Amy Kerrigan (b) (4)	12 Oct 2020 16:41:52
	(b) (4)	

US3782073

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:30:25
User entered '1'	System	12 Oct 2020 16:41:52

US3782073

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	21 Oct 2020 13:44:22

US3782073

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	(b) (4) System	14 Dec 2020 14:25:58
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	14 Dec 2020 14:19:42
User entered '21 Oct 2020'	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:44:22

US3782073

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:40

[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 19:46:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Clinic (Clinic)'	(b) (4) Carlton Griffin (b) (4)	21 Oct 2020 13:44:22

US3782073

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:32:40

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User entered 'VISIT3'	System	21 Oct 2020 13:44:22

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	14 Dec 2020 14:25:58
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 14:19:42
User entered '21 Oct 2020'	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '08:30'	(b) (4) Carlton Griffin (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User entered '21 Oct 2020 08:30'	System	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '98.0' F	Carlton Griffin (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Oral (Oral)'	(b) (4) Carlton Griffin (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered empty.	(b) (4) Carlton Griffin (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '60'	(b) (4) Carlton Griffin (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User entered 'bpm'	System	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '16'	Carlton Griffin (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User entered 'breaths/min'	System	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '117'	Carlton Griffin (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User entered 'mmHg'	System	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '70'	Carlton Griffin (b) (4)	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User entered 'mmHg'	System	21 Oct 2020 13:46:00

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55

US3782073

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:32:40

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55

US3782073

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	21 Oct 2020 13:44:12

US3782073

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:32:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4)	14 Dec 2020 14:25:58
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	14 Dec 2020 14:19:42
User entered '21 Oct 2020'	Carlton Griffin (b) (4)	21 Oct 2020 13:44:12
	(b) (4)	

US3782073

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	21 Oct 2020 13:46:13

US3782073

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	14 Dec 2020 14:25:58
User entered '21 Oct 2020'	System	14 Dec 2020 14:19:42
	Carlton Griffin (b) (4)	21 Oct 2020 13:46:13
	(b) (4)	

US3782073

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered '08:41'	(b) (4) Carlton Griffin (b) (4)	21 Oct 2020 13:46:13

US3782073

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:32:40

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User entered '21 Oct 2020 08:41'	System	21 Oct 2020 13:46:13

US3782073

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:16:44
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	21 Oct 2020 13:44:02

US3782073

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:46:55
User entered '1'	System	21 Oct 2020 13:44:02

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 64'	System	24 Aug 2020 13:56:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-10-24T00:01:48', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'cf1253b3-d82c-44cd-bc75-459435347448'	System	24 Oct 2020 05:02:19
User entered 'No (N)'	System	24 Oct 2020 05:02:19

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

Have you been exposed to someone with 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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-10-24T00:02:10', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'cf1253b3-d82c-44cd-bc75-459435347448'	System	24 Oct 2020 05:02:19
User entered 'No (N)'	System	24 Oct 2020 05:02:19

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-10-24T00:02:15', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'cf1253b3-d82c-44cd-bc75-459435347448' User entered '24 Oct 2020 00:02:15'	System	24 Oct 2020 05:02:19
	System	24 Oct 2020 05:02:19

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 13:56:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 71'	System	24 Aug 2020 13:56:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-03T08:28:08', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '5fed8e05-cc4a-471f-9444-f63c2c990747'	System	03 Nov 2020 14:28:30
User entered 'Yes (Y)'	System	03 Nov 2020 14:28:30

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

Have you been exposed to someone with 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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-03T08:28:12', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '5fed8e05-cc4a-471f-9444-f63c2c990747'	System	03 Nov 2020 14:28:30
User entered 'No (N)'	System	03 Nov 2020 14:28:30

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-03T08:28:16', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '5fed8e05-cc4a-471f-9444-f63c2c990747'	System	03 Nov 2020 14:28:30
User entered 'No (N)'	System	03 Nov 2020 14:28:30

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-03T08:28:23', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '5fed8e05-cc4a-471f-9444-f63c2c990747'	System	03 Nov 2020 14:28:30
User entered 'No (N)'	System	03 Nov 2020 14:28:30

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-03T08:28:28', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '5fed8e05-cc4a-471f-9444-f63c2c990747' User entered '03 Nov 2020 08:28:28'	System	03 Nov 2020 14:28:30
	System	03 Nov 2020 14:28:30

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 13:56:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered 'Day 78'	System	24 Aug 2020 13:56:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-07T00:01:44', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6c57d70c-dc12-43d4-8a10-9faf064e3b26'	System	07 Nov 2020 06:03:20
User entered 'No (N)'	System	07 Nov 2020 06:03:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

Have you been exposed to someone with 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 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-07T00:01:49', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6c57d70c-dc12-43d4-8a10-9faf064e3b26'	System	07 Nov 2020 06:03:20
User entered 'No (N)'	System	07 Nov 2020 06:03:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-07T00:02:19', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '6c57d70c-dc12-43d4-8a10-9faf064e3b26' User entered '07 Nov 2020 00:02:19'	System	07 Nov 2020 06:03:20
	System	07 Nov 2020 06:03:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 13:56:20

US3782073

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:52:46
Data entry locked.	System	24 Aug 2020 13:56:20
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 13:56:20

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[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)	02 May 2021 17:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-21T09:43:37', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e7397c22-4419-48fb-8443-195789398ac5' User entered 'No (N)'	System	21 Nov 2020 15:43:54
	System	21 Nov 2020 15:43:54

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

Have you been exposed to someone with 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)	02 May 2021 17:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-21T09:43:47', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e7397c22-4419-48fb-8443-195789398ac5' User entered 'No (N)'	System	21 Nov 2020 15:43:54
	System	21 Nov 2020 15:43:54

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-21T09:43:52', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'e7397c22-4419-48fb-8443-195789398ac5' User entered '21 Nov 2020 09:43:52'	System	21 Nov 2020 15:43:54
	System	21 Nov 2020 15:43:54

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[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)	02 May 2021 17:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-25T02:23:40', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd053f437-130c-48e0-bb4b-08c485f01465'	System	25 Nov 2020 08:23:51
User entered 'No (N)'	System	25 Nov 2020 08:23:51

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

Have you been exposed to someone with 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)	02 May 2021 17:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-25T02:23:45', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd053f437-130c-48e0-bb4b-08c485f01465'	System	25 Nov 2020 08:23:51
User entered 'No (N)'	System	25 Nov 2020 08:23:51

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-11-25T02:23:48', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'd053f437-130c-48e0-bb4b-08c485f01465' User entered '25 Nov 2020 02:23:48'	System	25 Nov 2020 08:23:51
	System	25 Nov 2020 08:23:51

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[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)	02 May 2021 17:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-12-02T00:20:40', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'ca204465-de44-4f48-b129-b9b23715ed47'	System	02 Dec 2020 06:21:00
User entered 'No (N)'	System	02 Dec 2020 06:21:00

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

Have you been exposed to someone with 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)	02 May 2021 17:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-12-02T00:20:52', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'ca204465-de44-4f48-b129-b9b23715ed47'	System	02 Dec 2020 06:21:00
User entered 'No (N)'	System	02 Dec 2020 06:21:00

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-12-02T00:20:58', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: 'ca204465-de44-4f48-b129-b9b23715ed47' User entered '02 Dec 2020 00:20:58'	System	02 Dec 2020 06:21:00
	System	02 Dec 2020 06:21:00

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[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)	02 May 2021 17:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-12-09T18:37:09', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '924a7f09-c6ee-4ec9-833f-6b15b4cd0221'	System	10 Dec 2020 00:37:27
User entered 'No (N)'	System	10 Dec 2020 00:37:27

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

Have you been exposed to someone with 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)	02 May 2021 17:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-12-09T18:37:16', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '924a7f09-c6ee-4ec9-833f-6b15b4cd0221'	System	10 Dec 2020 00:37:27
User entered 'No (N)'	System	10 Dec 2020 00:37:27

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-12-09T18:37:24', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '924a7f09-c6ee-4ec9-833f-6b15b4cd0221' User entered '09 Dec 2020 18:37:24'	System	10 Dec 2020 00:37:27
	System	10 Dec 2020 00:37:27

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
DataPoint Activated.	System	14 Dec 2020 14:25:58
DataPoint Inactivated.	System	14 Dec 2020 14:19:42
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

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)	02 May 2021 17:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-12-17T00:52:59', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '37aca763-84cc-45a8-b2a6-ab15e9616d67'	System	17 Dec 2020 06:53:12
User entered 'No (N)'	System	17 Dec 2020 06:53:12
DataPoint Activated.	System	14 Dec 2020 14:25:58
DataPoint Inactivated.	System	14 Dec 2020 14:19:42

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

Have you been exposed to someone with 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)	02 May 2021 17:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-12-17T00:53:05', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '37aca763-84cc-45a8-b2a6-ab15e9616d67'	System	17 Dec 2020 06:53:12
User entered 'No (N)'	System	17 Dec 2020 06:53:12
DataPoint Activated.	System	14 Dec 2020 14:25:58
DataPoint Inactivated.	System	14 Dec 2020 14:19:42

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-12-17T00:53:09', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '37aca763-84cc-45a8-b2a6-ab15e9616d67'	System	17 Dec 2020 06:53:12
User entered '17 Dec 2020 00:53:09'	System	17 Dec 2020 06:53:12
DataPoint Activated.	System	14 Dec 2020 14:25:58
DataPoint Inactivated.	System	14 Dec 2020 14:19:42

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
DataPoint Activated.	System	14 Dec 2020 14:25:58
DataPoint Inactivated.	System	14 Dec 2020 14:19:42
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
DataPoint Activated.	System	14 Dec 2020 14:25:58
DataPoint Inactivated.	System	14 Dec 2020 14:19:42
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
DataPoint Activated.	System	14 Dec 2020 14:25:58
DataPoint Inactivated.	System	14 Dec 2020 14:19:42
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

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)	02 May 2021 17:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-12-25T12:02:13', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '638f3eea-76f0-45ff-9724-0be3ffe875ac'	System	25 Dec 2020 18:02:24
User entered 'No (N)'	System	25 Dec 2020 18:02:24
DataPoint Activated.	System	14 Dec 2020 14:25:58
DataPoint Inactivated.	System	14 Dec 2020 14:19:42

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

Have you been exposed to someone with 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)	02 May 2021 17:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-12-25T12:02:17', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '638f3eea-76f0-45ff-9724-0be3ffe875ac'	System	25 Dec 2020 18:02:24
User entered 'No (N)'	System	25 Dec 2020 18:02:24
DataPoint Activated.	System	14 Dec 2020 14:25:58
DataPoint Inactivated.	System	14 Dec 2020 14:19:42

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (215587FF-8F89-4B98-87A5-353C3AF78F16)', Time: '2020-12-25T12:02:21', User OID: 'PatientReportedOutcome (US3782073)', ODM File OID: '638f3eea-76f0-45ff-9724-0be3ffe875ac'	System	25 Dec 2020 18:02:24
User entered '25 Dec 2020 12:02:21'	System	25 Dec 2020 18:02:24
DataPoint Activated.	System	14 Dec 2020 14:25:58
DataPoint Inactivated.	System	14 Dec 2020 14:19:42

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
DataPoint Activated.	System	14 Dec 2020 14:25:58
DataPoint Inactivated.	System	14 Dec 2020 14:19:42
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:33:36

US3782073

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
DataPoint Activated.	System	14 Dec 2020 14:25:58
DataPoint Inactivated.	System	14 Dec 2020 14:19:42
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:33:36
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:33:36

US3782073

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	16 Nov 2020 15:58:40

US3782073

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	14 Dec 2020 14:25:58
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 14:19:42
User entered '16 Nov 2020'	Carlton Griffin (b) (4)	16 Nov 2020 15:58:40
	(b) (4)	

US3782073

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4)	16 Nov 2020 15:58:40

US3782073

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	Carlton Griffin (b) (4)	16 Nov 2020 15:58:40

US3782073

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	16 Nov 2020 15:58:47

US3782073

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:26:53
User entered '1'	System	16 Nov 2020 15:58:47

US3782073

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:07:57

US3782073

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:07:57

US3782073

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:07:57

US3782073

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:32:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:07:57

US3782073

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:08:06

US3782073

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:32:40

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:28:55
User entered '1'	System	21 Dec 2020 21:08:06

US3782073

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:40

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:15:12
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	29 Mar 2021 19:07:21
	(b) (4)	

US3782073

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:40

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:15:12
	(b) (4)	
User entered '1'	Carlton Griffin (b) (4)	29 Mar 2021 19:07:21
	(b) (4)	

US3782073

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:40

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:15:12
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	29 Mar 2021 19:07:21
	(b) (4)	

US3782073

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:40

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:15:12
	(b) (4)	
User entered 'Amendment 5 (Amendment 5)'	Carlton Griffin (b) (4)	29 Mar 2021 19:07:21
	(b) (4)	

US3782073

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:40

[Date of unblinding \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:15:12
	(b) (4)	
User entered '24 Dec 2020'	Carlton Griffin (b) (4)	29 Mar 2021 19:07:21
	(b) (4)	

US3782073

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:40

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:15:12
	(b) (4)	
User entered 'Placebo (Placebo)'	Carlton Griffin (b) (4)	29 Mar 2021 19:07:21
	(b) (4)	

US3782073

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:40

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:15:12
	(b) (4)	
User entered 'Placebo (Placebo)'	Carlton Griffin (b) (4)	29 Mar 2021 19:07:21
	(b) (4)	

US3782073

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:40

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:15:12
	(b) (4)	
User entered 'Not Administered (NA)'	Carlton Griffin (b) (4)	29 Mar 2021 19:07:21
	(b) (4)	

US3782073

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:40

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:15:12
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	29 Mar 2021 19:07:21
	(b) (4)	

US3782073

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:40

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User entered '1'	System	29 Mar 2021 19:07:21

US3782073

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

Form: Unblinding

Generated On: 12 Aug 2021 13:32:40

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User entered empty.	System	29 Mar 2021 19:07:21

US3782073

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:32:40

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Aug 2020 19:04:40

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Otherwise, specify the anatomical location of ANGIOEDEMA. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:40:17
Query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Otherwise, specify the anatomical location of ANGIOEDEMA. ' answered with 'no known underlying medical condition. see narrative below for location of angioedema ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	03 Nov 2020 14:10:20
User opened query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Otherwise, specify the anatomical location of ANGIOEDEMA. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 06:30:15
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Angioedemas, PT: Angioedema, LLT: Angioedema - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:45:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:45:47
Data point term sent to Coder	System	21 Sep 2020 22:15:50
Coding entries removed.	(b) (4), (b) (6)	21 Sep 2020 22:15:01
User entered 'ANGIOEDEMA' reason for change: New Information	(b) (4), (b) (6)	21 Sep 2020 22:15:01

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Oral soft tissue conditions, HLT: Oral soft tissue swelling and oedema, PT: Mouth swelling, LLT: Oral mucosa swollen - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:43:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 15:43:48
Data point term sent to Coder	System	08 Sep 2020 15:23:22
Coding entries removed.	(b) (4), (b) (6)	08 Sep 2020 15:23:07
User entered 'Angiodema localized to oral mucosa' reason for change: New Information	(b) (4), (b) (6)	08 Sep 2020 15:23:07
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Food allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 20:51:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Aug 2020 20:51:37
Data point term sent to Coder	System	30 Aug 2020 19:08:59
User entered 'allergic reaction - likely to food'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	26 Oct 2020 20:58:34
User entered 'No (N)'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the AE term is not one of the protocol defined Solicited AR. Please review and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 12:27:53
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the AE term is not one of the protocol defined Solicited AR. Please review and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Carlton Griffin (b) (4)	24 Sep 2020 18:48:32
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	24 Sep 2020 18:47:56
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the AE term is not one of the protocol defined Solicited AR. Please review and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:37:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered '28 Aug 2020'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	30 Aug 2020 19:09:07
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Aug 2020 19:09:07
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	30 Aug 2020 19:08:27
User entered '18:45'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User entered empty.	System	30 Aug 2020 19:09:07
User entered '28 Aug 2020 18:45'	System	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 17:06:15
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'confirmed that it is still ongoing' (Site from DM).	Carlton Griffin (b) (4)	30 Nov 2020 15:54:49
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 02:40:41
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	21 Sep 2020 22:15:01
User entered 'No (N)'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered empty; reason for change New Information	(b) (4), (b) (6)	21 Sep 2020 22:15:01
User entered '30 Aug 2020'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	30 Aug 2020 19:09:20
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Aug 2020 19:09:20
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	30 Aug 2020 19:08:27
User entered '07:00'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User entered empty.	System	30 Aug 2020 19:09:20
User entered '30 Aug 2020 07:00'	System	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:30:20
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	21 Sep 2020 22:15:01
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 14:03:07
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'INVESTIGATIONAL PRODUCT WITHDRAWN PER PHYSICIAN DECISION' (Site from System).	Carlton Griffin (b) (4)	24 Sep 2020 18:48:23
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	23 Sep 2020 13:14:59
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	(b) (4), (b) (6)	21 Sep 2020 22:15:01
User entered 'None (NONE)'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered '1'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	21 Sep 2020 22:15:01
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Aug 2020 19:09:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Aug 2020 19:09:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Aug 2020 19:09:36
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Aug 2020 19:08:27
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'angioedema located on oral mucosa, right hip, and buttock' reason for change: New Information	Carlton Griffin (b) (4)	28 Oct 2020 15:29:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User entered '0'	System	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User entered '1'	System	26 Oct 2020 20:58:34
User entered '0'	System	30 Aug 2020 19:08:27

US3782073

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:32:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Malaise, LLT: Malaise - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 15:25:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 15:25:45
Data point term sent to Coder	System	08 Sep 2020 15:24:24
User entered 'malaise'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the AE term is not one of the protocol defined Solicited AR. Please review and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 12:28:12
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the AE term is not one of the protocol defined Solicited AR. Please review and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	24 Sep 2020 18:49:19
User entered 'No (N)' reason for change: Data Entry Error	Carlton Griffin (b) (4) (b) (4)	24 Sep 2020 18:49:13
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the AE term is not one of the protocol defined Solicited AR. Please review and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 14:37:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User entered empty.	System	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User entered empty.	System	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '1'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Sep 2020 15:24:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 15:24:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	08 Sep 2020 15:24:33
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:24:20
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User entered '0'	System	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56
User entered '0'	System	08 Sep 2020 15:24:20

US3782073

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:32:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:12:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:32:40

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'Yes (Y)'	Amber Massey (b) (4)	24 Aug 2020 13:57:38
	(b) (4)	

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORETHISTERONE ACETATE, PRODUCTSYNONYM: MICROGESTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Oct 2020 18:57:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Oct 2020 18:57:41
Data point term sent to Coder	System	21 Oct 2020 18:56:59
Coding entries removed.	Carlton Griffin (b) (4)	21 Oct 2020 18:56:11
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORETHISTERONE ACETATE, PRODUCTSYNONYM: MICROGESTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 18:07:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Aug 2020 18:07:06
Data point term sent to Coder	System	24 Aug 2020 13:58:33
User entered 'microgestin'	Amber Massey (b) (4)	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'Yes (Y)'	Amber Massey (b) (4)	24 Aug 2020 13:58:21
	(b) (4)	

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Per CDM: Please reconcile with Med History eCRF so there is an appropriate condition recorded.	(b) (4), (b) (6)	11 Nov 2020 15:49:04
' (Site from DM). Query 'Per CDM: Please reconcile with Med History eCRF so there is an appropriate condition recorded.	Carlton Griffin (b) (4)	29 Oct 2020 17:59:36
' answered with 'no condition associated with taking a contraceptive' (Site from DM). User opened query 'Per CDM: Please reconcile with Med History eCRF so there is an appropriate condition recorded.	(b) (4), (b) (6)	28 Oct 2020 18:24:37
' (Site from DM). 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 (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded.	(b) (4), (b) (6)	28 Oct 2020 18:23:16
' (Site from DM). Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded.	Carlton Griffin (b) (4)	21 Oct 2020 18:56:21
' answered with 'updated- thanks! ' (Site from DM). User entered 'contraception' reason for change: Per Query Resolution	Carlton Griffin (b) (4)	21 Oct 2020 18:56:11
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 (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:55:12

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'oral contraceptive'	Amber Massey (b) (4) (b) (4)	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered '1'	Amber Massey (b) (4)	24 Aug 2020 13:58:21
	(b) (4)	

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'tablet (TABLET)'	Amber Massey (b) (4)	24 Aug 2020 13:58:21
	(b) (4)	

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	24 Aug 2020 13:58:21
	(b) (4)	

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'once daily (QD)'	Amber Massey (b) (4)	24 Aug 2020 13:58:21
	(b) (4)	

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	24 Aug 2020 13:58:21
	(b) (4)	

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Massey (b) (4)	24 Aug 2020 13:58:21
	(b) (4)	

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	24 Aug 2020 13:58:21
	(b) (4)	

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'un Oct 2010'	Amber Massey (b) (4)	24 Aug 2020 13:58:21
	(b) (4)	

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered '0'	Amber Massey (b) (4)	24 Aug 2020 13:58:21
	(b) (4)	

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'Yes (Y)'	Amber Massey (b) (4)	24 Aug 2020 13:58:21
	(b) (4)	

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	24 Aug 2020 13:58:21
	(b) (4)	

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'No (N)'	Amber Massey (b) (4)	24 Aug 2020 13:58:21
	(b) (4)	

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User entered '1'	System	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User entered '1'	System	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User entered '804 (804)'	System	24 Aug 2020 13:58:21

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:40

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:22
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Oct 2020 17:33:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Oct 2020 17:33:39
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: ACRIVASTINE, PRODUCTSYNONYM: BENADRYL [ACRIVASTINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Sep 2020 22:10:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Sep 2020 22:10:39
Data point term sent to Coder	System	22 Sep 2020 14:00:47
Coding entries removed.	(b) (4), (b) (6)	22 Sep 2020 13:59:57
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIHISTAMINES FOR TOPICAL USE, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 23:12:00

PRODUCTION RELEASE (v12.003
EAB) (1725)

839 of 996

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6)	08 Sep 2020 23:12:00 08 Sep 2020 15:26:32 08 Sep 2020 15:26:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 04:48:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. Data point term sent to Coder User entered 'Benadryl'	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6)	31 Aug 2020 04:48:44 30 Aug 2020 19:11:02 30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:22
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:22
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' answered with 'see updated AE narrative for location of angioedema. AE is not solicited. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:50:04
User opened query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM).	Carlton Griffin (b) (4)	28 Oct 2020 15:30:24
User entered 'ANGIOEDEMA' reason for change: New Information	(b) (4)	
User entered 'Angioedema localized to oral mucosa' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 14:15:54
User entered 'likely food allergy'	(b) (4), (b) (6)	22 Sep 2020 13:59:57
	(b) (4), (b) (6)	08 Sep 2020 15:26:12
	(b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:22
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '50'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:22
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:22
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:22
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:22
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:22
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:40

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:22
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:22
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:22
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:22
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:22
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	30 Aug 2020 19:11:55
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Aug 2020 19:11:55
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	30 Aug 2020 19:10:53
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:22
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:11:45
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' answered with 'updated' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 14:28:07
User entered 'No (N)' reason for change: Data Entry Error	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 14:27:48
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:55:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:22
User entered empty.	System	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:22
User entered empty.	System	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:22
User entered empty.	System	30 Aug 2020 19:10:53

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Sep 2020 14:01:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Sep 2020 14:01:43
Data point term sent to Coder Coding entries removed.	System	22 Sep 2020 14:00:47
	(b) (4), (b) (6)	22 Sep 2020 14:00:25
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 18:09:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 18:09:46
Data point term sent to Coder Coding entries removed.	System	08 Sep 2020 15:26:33
	(b) (4), (b) (6)	08 Sep 2020 15:26:31
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	31 Aug 2020 04:53:55

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Famotidine'	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6)	31 Aug 2020 04:53:55 30 Aug 2020 19:12:04 30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' answered with 'see updated AE narrative for location of angioedema. AE is not solicited. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:51:08
User opened query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM).	Carlton Griffin (b) (4)	28 Oct 2020 15:31:50
User entered 'ANGIOEDEMA' reason for change: New Information	(b) (4)	
User entered 'Angioedema localized to oral mucosa' reason for change: New Information	(b) (4), (b) (6)	27 Oct 2020 14:16:21
User entered 'likely food allergy'	(b) (4), (b) (6)	22 Sep 2020 14:00:25
	(b) (4), (b) (6)	08 Sep 2020 15:26:31
	(b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '20'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:40

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	30 Aug 2020 19:11:36
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Aug 2020 19:11:36
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	30 Aug 2020 19:11:26
User entered empty.	(b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:12:00
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' answered with 'updated ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 14:28:35
User entered 'No (N)' reason for change: Data Entry Error	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 14:28:29
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:55:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:36
User entered empty.	System	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:36
User entered empty.	System	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:36
User entered empty.	System	30 Aug 2020 19:11:26

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 14:33:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 14:33:59
Data point term sent to Coder Coding entries removed.	System	22 Sep 2020 14:01:50
	(b) (4), (b) (6)	22 Sep 2020 14:00:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 06:49:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 06:49:36
Data point term sent to Coder Coding entries removed.	System	08 Sep 2020 15:26:26
	(b) (4), (b) (6)	08 Sep 2020 15:25:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 05:03:48

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Naproxen'	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6)	31 Aug 2020 05:03:48 30 Aug 2020 19:15:05 30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	11 Nov 2020 15:51:19
Query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' answered with 'see updated AE narrative for location of angioedema. AE is not solicited. ' (Site from DM).	Carlton Griffin (b) (4)	28 Oct 2020 15:31:59
User opened query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:17:23
User entered 'ANGIOEDEMA' reason for change: New Information	(b) (4), (b) (6)	22 Sep 2020 14:00:54
User entered 'Angioedema localized to oral mucosa' reason for change: New Information	(b) (4), (b) (6)	08 Sep 2020 15:25:39
User entered 'likely food allergy'	(b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '220'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:40

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '29 Aug 2020'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '29 Aug 2020'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:12:13
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' answered with 'updated' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 14:28:54
User entered 'No (N)' reason for change: Data Entry Error	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 14:28:49
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:55:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:29
User entered '2'	System	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:29
User entered '1'	System	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:29
User entered '804 (804)'	System	30 Aug 2020 19:14:56

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:51:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Sep 2020 16:09:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 16:09:48
Data point term sent to Coder	System	08 Sep 2020 15:28:34
User entered 'naproxen'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:51:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:51:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'malaise'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:51:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '220'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:51:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:51:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:51:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:51:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:51:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:40

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:51:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:51:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:51:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:51:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:51:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '28 Aug 2020'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:51:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:12:28
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' answered with 'updated' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 14:29:11
User entered 'No (N)' reason for change: Data Entry Error	Carlton Griffin (b) (4) (b) (4)	21 Oct 2020 14:29:06
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:56:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:51:11
User entered '1'	System	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:51:11
User entered '1'	System	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:51:11
User entered '804 (804)'	System	08 Sep 2020 15:27:34

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	22 Sep 2020 01:03:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 01:03:51
Data point term sent to Coder	System	21 Sep 2020 22:04:30
User entered 'famotidine'	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' answered with 'see updated AE narrative for location of angioedema. AE is not solicited. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:51:31
User opened query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM). User entered 'angioedema'	Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 15:32:07
	(b) (4), (b) (6)	27 Oct 2020 14:16:53
	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '20'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:40

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '12 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '12 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:50
User entered empty.	System	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:50
User entered empty.	System	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:50
User entered empty.	System	21 Sep 2020 22:03:39

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 22:05:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 22:05:51
Data point term sent to Coder	System	21 Sep 2020 22:05:30
User entered 'allegra'	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' answered with 'see updated AE narrative for location of angioedema. AE is not solicited. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 15:51:43
User opened query 'Per DM CLR: Please specify location of ANGIOEDEMA and determine if the edema is a solicited AE. If so, reconcile with AE eCRF and in the last field of this eCRF. Update as appropriate. Otherwise, clarify.' (Site from DM). User entered 'angioedema'	Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 15:32:15
	(b) (4), (b) (6)	27 Oct 2020 14:15:30
	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '180'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:40

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:58
User entered empty.	System	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:58
User entered empty.	System	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:58
User entered empty.	System	21 Sep 2020 22:04:37

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:44
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
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)	12 Oct 2020 16:45:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Oct 2020 16:45:19
Data point term sent to Coder	System	12 Oct 2020 16:44:05
User entered 'Influenza Vaccine'	Amy Kerrigan (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:44
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Yes (Y)'	(b) (4) Amy Kerrigan (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:44
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Influenza Prophylaxis'	Amy Kerrigan (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:44
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0.5'	(b) (4) Amy Kerrigan (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:44
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'mL (mL)'	Amy Kerrigan (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:44
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Amy Kerrigan (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:44
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'once (ONCE)'	(b) (4) Amy Kerrigan (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:44
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Amy Kerrigan (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:44
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'Intramuscular (INTRAMUSCULAR)'	Amy Kerrigan (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:40

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:44
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	Amy Kerrigan (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:44
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	14 Dec 2020 14:25:58
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 14:19:42
User entered '5 Oct 2020'	Amy Kerrigan (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:44
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '0'	Amy Kerrigan (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:44
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	Amy Kerrigan (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:44
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4)	14 Dec 2020 14:25:58
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	14 Dec 2020 14:19:42
User entered '5 Oct 2020'	Amy Kerrigan (b) (4)	12 Oct 2020 16:43:40
	(b) (4)	

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:44
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'No (N)'	(b) (4) Amy Kerrigan (b) (4)	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:44
User entered empty.	System	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:44
User entered empty.	System	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:50:44
User entered empty.	System	12 Oct 2020 16:43:40

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Oct 2020 14:11:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Oct 2020 14:11:41
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 14:10:26
User entered 'multivitamin'	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Per DM CLR-Requery: Response noted. However, please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 19:36:56
Query 'Per DM CLR-Requery: Response noted. However, please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Carlton Griffin (b) (4)	04 Jan 2021 12:44:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Carlton Griffin (b) (4)	04 Jan 2021 12:44:02
User opened query 'Per DM CLR-Requery: Response noted. However, please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Jan 2021 19:33:34
User closed query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:51:55
Query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'medication not prophylactic or preventative. not associated with a diagnosis. ' (Site from DM).	Carlton Griffin (b) (4)	30 Oct 2020 13:16:00
User opened query 'Per CDM: Response is recorded as No; however, indication suggests this is being used as prophylaxis. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 18:52:54
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'general health'	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered '1'	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:40

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Oct 2020 14:10:41
User entered 'UN UNK 2000' reason for change:	(b) (4), (b) (6)	21 Oct 2020 14:10:41
Data Entry Error		
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Oct 2020 14:10:25
User entered 'un 2000' (non-conformant).	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User entered '1'	System	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User entered '1'	System	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User entered '804 (804)'	System	21 Oct 2020 14:10:25

US3782073

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:32:40

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:28
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:27:52
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	19 Feb 2021 20:45:53
	(b) (4)	

US3782073

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:32:40

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:21:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Per CDM: Please complete EOS/Study Discontinuation.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please complete EOS/Study Discontinuation.' answered with 'completed' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 18:48:07
User opened query 'Per CDM: Please complete EOS/Study Discontinuation.' (Site from DM).	Carlton Griffin (b) (4)	14 Dec 2020 14:19:51
User entered '21 Sep 2020'	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 19:31:00
	(b) (4), (b) (6)	23 Sep 2020 13:14:59

US3782073

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:32:40

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:21:55
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:43
User closed query 'Per CDM: There is an AE recorded as IP withdrawn. Please consider updating this field to AE (Specify). Please then update the reason for the corresponding AE Logline #. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:20:12
Query 'Per CDM: There is an AE recorded as IP withdrawn. Please consider updating this field to AE (Specify). Please then update the reason for the corresponding AE Logline #. ' answered with 'updated, thanks' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	12 Apr 2021 18:48:32
Signature has been broken.	Carlton Griffin (b) (4) (b) (4)	12 Apr 2021 18:48:11
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Per Query Resolution	Carlton Griffin (b) (4) (b) (4)	12 Apr 2021 18:48:11
User opened query 'Per CDM: There is an AE recorded as IP withdrawn. Please consider updating this field to AE (Specify). Please then update the reason for the corresponding AE Logline #. ' (Site from DM).	(b) (4), (b) (6)	11 Apr 2021 16:40:48
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:14:33
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	(b) (4), (b) (6)	23 Sep 2020 13:14:59

US3782073

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:21:55
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:42:43
Signature has been broken.	Carlton Griffin (b) (4)	12 Apr 2021 18:48:11
User entered 'AE #1' reason for change: Per Query Resolution	Carlton Griffin (b) (4)	12 Apr 2021 18:48:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'see ePip; history of new onset angioedema'	(b) (4), (b) (6)	23 Sep 2020 13:14:59

US3782073

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:32:40

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:21:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	30 Dec 2020 06:29:16
User entered '24 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	26 Dec 2020 15:54:33
Query 'Data is required. Please complete.' answered with 'inadvertantly entered data. participant was not discontinued from the study. second dose of IP was discontinued.' (Site from System).	Carlton Griffin (b) (4)	14 Dec 2020 14:26:30
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 14:25:58
User entered empty; reason for change Data Entry Error	Carlton Griffin (b) (4)	14 Dec 2020 14:25:58
	(b) (4)	
User entered '21 Sep 2020'	Carlton Griffin (b) (4)	14 Dec 2020 14:19:42
	(b) (4)	

US3782073

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:32:40

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:21:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	30 Dec 2020 06:29:18
User entered 'Other (OTHER)' reason for change: New Information	(b) (4), (b) (6)	26 Dec 2020 15:54:33
Query 'Data is required. Please complete.' answered with 'inadvertantly entered data. participant was not discontinued from the study. second dose of IP was discontinued.' (Site from System).	Carlton Griffin (b) (4)	14 Dec 2020 14:26:34
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 14:25:58
User entered empty; reason for change Data Entry Error	Carlton Griffin (b) (4)	14 Dec 2020 14:25:58
	(b) (4)	
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Carlton Griffin (b) (4)	14 Dec 2020 14:19:42
	(b) (4)	

US3782073

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:32:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:21:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered 'PARTICIPANT HAS BEEN UNBLINDED. REASON: OTHER – REQUEST TO UNBLIND / EUA COVID-19 VACCINE' reason for change: New Information	(b) (4) (b) (4), (b) (6)	26 Dec 2020 15:54:33
User entered empty; reason for change Data Entry Error	Carlton Griffin (b) (4)	14 Dec 2020 14:25:58
User entered 'see epip; history of new onset angioedema'	(b) (4) Carlton Griffin (b) (4)	14 Dec 2020 14:19:42

US3782073

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:32:40

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:21:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Carlton Griffin (b) (4)	14 Dec 2020 14:19:42

US3782073

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:32:40

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:21:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Carlton Griffin (b) (4)	14 Dec 2020 14:19:42

US3782073

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:32:40

[Date of death \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:21:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Carlton Griffin (b) (4)	14 Dec 2020 14:19:42

US3782073

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:32:40

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:21:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:14:33
User entered empty.	(b) (4) Carlton Griffin (b) (4)	14 Dec 2020 14:19:42