

US3782162 (Prod: Vanderbilt University Medical Center)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3782162

Form: Participant Creation

Data signed: (b) (4) 26 Jan 2021 20:30:00

Generated On: 10 Jun 2021 09:45:13

[Participant ID](#)

US3782162

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

US3782162

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Date of Birth (MMM yyyy)	(b) (6) 1941
Age	78
Age Units	YEARS
Age (Derived)	78
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Date of Informed Consent (<i>dd MMM yyyy</i>)	8 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 23:32:58

Generated On: 10 Jun 2021 09:45:13

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 23:32:58

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 23:32:58

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 23:32:58

Generated On: 10 Jun 2021 09:45:13

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 23:32:58

Generated On: 10 Jun 2021 09:45:13

Condition	BPH
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 23:32:58

Generated On: 10 Jun 2021 09:45:13

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 23:32:58

Generated On: 10 Jun 2021 09:45:13

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 23:32:58

Generated On: 10 Jun 2021 09:45:13

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 23:32:58

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 23:32:58

Generated On: 10 Jun 2021 09:45:13

Condition	ANGINA
Start date (dd MMM yyyy)	30 OCT 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	13:06 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 13:06
Height (xxx.x)	161.5 cm
Weight (xxx.x)	76.9 kg
BMI (xxx.x)	29.48365 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Jan 2021 20:30:04

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Jan 2021 20:30:04

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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	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

What was the date of randomization? (dd MMM yyyy) 08 SEP 2020

What was the participant's randomization number? 190005

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	13:06 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 13:06
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	14:13 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 14:13
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	57 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 13:43 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 13:43

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 SEP 2020
Collection time (00:00-23:59)	13:18 (24 HR)
Collection date and time (derived)	08 SEP 2020 13:18

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:21	08 SEP 2020 13:21
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 14:17

PC Open Date & Time

08 SEP 2020 14:03

PC Close Date & Time

08 SEP 2020 16:33

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.2 °F

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

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

PC Time Stamp	08 SEP 2020 18:46
PC Open Date & Time	08 SEP 2020 17:28
PC Close Date & Time	09 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:13

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

99.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 19:15

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 17:51

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:13

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 18:55

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:13

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

97.6 °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

13 SEP 2020 08:12

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

13 SEP 2020 21:24

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 19:41

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

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

08 SEP 2020 14:18

PC Open Date & Time

08 SEP 2020 14:03

PC Close Date & Time

08 SEP 2020 16:33

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 18:47

PC Open Date & Time

08 SEP 2020 17:28

PC Close Date & Time

09 SEP 2020 11:59

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 19:16

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:13

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

10 SEP 2020 17:52

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:13

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

11 SEP 2020 18:56

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:13

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

13 SEP 2020 08:12

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:13

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

13 SEP 2020 21:25

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:13

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

14 SEP 2020 19:41

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

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 ☐

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 14:18
PC Open Date & Time	08 SEP 2020 14:03
PC Close Date & Time	08 SEP 2020 16:33

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

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 ☐

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 18:48
PC Open Date & Time	08 SEP 2020 17:28
PC Close Date & Time	09 SEP 2020 11:59

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

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 ☒

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EAB) (1725)

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 19:17
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

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

53 of 2519

EAB) (1725)

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 17:53
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

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 ☒

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 18:57
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

57 of 2519

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 08:12
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

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

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EAB) (1725)

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 21:26
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

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 ☒

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 19:42
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3782162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782162

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782162

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

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

Visit date (dd MMM yyyy)	9 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 OCT 2020
Time of assessment (00:00-23:59)	12:08 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 12:08
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	9 OCT 2020
Time of assessment (00:00-23:59)	13:21 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 13:21
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	55 mmHg
Diastolic Blood Pressure units	MMHG

US3782162

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 OCT 2020

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

US3782162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

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) 9 OCT 2020

What was the treatment time? (00:00-23:59) 12:50 (24 HR)

Treatment Date and Time (derived) 9 OCT 2020 12:50

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

US3782162

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 OCT 2020

Collection time (00:00-23:59)

12:20 (24 HR)

Collection date and time (derived)

9 OCT 2020 12:20

US3782162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Collection date (dd MMM yyyy)			9 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:25	9 OCT 2020 12:25
Nasopharyngeal Swab 2	No		

US3782162

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

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

98.0 °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

09 OCT 2020 13:25

PC Open Date & Time

09 OCT 2020 13:10

PC Close Date & Time

09 OCT 2020 15:40

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

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 97.7 °F

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

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

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 09 OCT 2020 19:11

PC Open Date & Time 09 OCT 2020 16:35

PC Close Date & Time 10 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 20:25

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

11 OCT 2020 20:53

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

12 OCT 2020 20:10

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:13

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

13 OCT 2020 19:41

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:13

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

14 OCT 2020 20:27

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

15 OCT 2020 20:13

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 8

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

17 OCT 2020 10:08

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

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

09 OCT 2020 13:26

PC Open Date & Time

09 OCT 2020 13:10

PC Close Date & Time

09 OCT 2020 15:40

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 19:11

PC Open Date & Time

09 OCT 2020 16:35

PC Close Date & Time

10 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 OCT 2020 20:26

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:13

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

11 OCT 2020 20:54

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:13

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

12 OCT 2020 20:10

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:13

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

13 OCT 2020 19:41

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:13

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

14 OCT 2020 20:28

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:13

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

15 OCT 2020 20:14

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

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 ☐

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 13:26
PC Open Date & Time	09 OCT 2020 13:10
PC Close Date & Time	09 OCT 2020 15:40

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

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 ☐

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 19:12
PC Open Date & Time	09 OCT 2020 16:35
PC Close Date & Time	10 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

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 ☒

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 20:27
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

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 ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 20:54
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

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 ☒

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 20:11
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

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 ☒

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 19:42
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

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 ☐

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

	Yes <input type="checkbox"/>
PC Time stamp	14 OCT 2020 20:29
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

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 ☐

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

		Yes <input type="checkbox"/>
PC Time stamp	15 OCT 2020 20:14	
PC Open Date & Time	15 OCT 2020 12:00	
PC Close Date & Time	16 OCT 2020 11:59	

US3782162

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 OCT 2020 10:08
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3782162

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782162

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782162

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782162

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 NOV 2020
Time of assessment (00:00-23:59)	09:32 (24 HR)
Vital Signs Date and Time (derived)	6 NOV 2020 09:32
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	53 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3782162

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 NOV 2020

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

US3782162

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

6 NOV 2020

Collection time (00:00-23:59)

09:50 (24 HR)

Collection date and time (derived)

6 NOV 2020 09:50

US3782162

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

09 NOV 2020 10:14:24

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3782162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 17:46:58

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 11:25:28
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 NOV 2020 13:38:38

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

Date and time of submission

Patient Cloud Open Date & Time	03 DEC 2020 00:01
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Patient Cloud Close Date & Time	07 DEC 2020 23:59
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US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 12:12:42
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

18 DEC 2020 14:36:21

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

24 DEC 2020 13:51:24

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

02 JAN 2021 10:57:25

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

07 JAN 2021 14:54:14

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 13:58:16

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	22 JAN 2021 09:34:26
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 07:47:54

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 11:24:15

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 15:55:21

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 19:11:48

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 10:05:55

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 MAR 2021 09:50:31
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 10:11:42

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	18 MAR 2021 08:31:56
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	01 APR 2021 08:55:41
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	08 APR 2021 12:40:43
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 09:09:32

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 08:52:50

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 10:10:37

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

Patient Cloud Open Date & Time	12 AUG 2021 00:01
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Patient Cloud Close Date & Time	16 AUG 2021 23:59
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US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

Patient Cloud Open Date & Time	26 AUG 2021 00:01
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Patient Cloud Close Date & Time	30 AUG 2021 23:59
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US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2021 00:01
Patient Cloud Close Date & Time	11 OCT 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

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14 FEB 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

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07 MAR 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

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21 MAR 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

Patient Cloud Open Date & Time	25 AUG 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 761

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

Patient Cloud Open Date & Time	20 OCT 2022 00:01
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Patient Cloud Close Date & Time	24 OCT 2022 23:59
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US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2022 00:01
Patient Cloud Close Date & Time	31 OCT 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2022 23:59

US3782162

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:45:13

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 13:20:54

US3782162

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:30:04

Generated On: 10 Jun 2021 09:45:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782162

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782162

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782162

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782162

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:32:58

Generated On: 10 Jun 2021 09:45:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782162

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:32:58

Generated On: 10 Jun 2021 09:45:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782162

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 01:21:23

Generated On: 10 Jun 2021 09:45:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3782162

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 01:21:23

Generated On: 10 Jun 2021 09:45:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782162

Folder: Visit 4 Day 209 (1)

Form: Visit Date

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

Generated On: 10 Jun 2021 09:45:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3782162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

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

Generated On: 10 Jun 2021 09:45:13

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3782162

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

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

Generated On: 10 Jun 2021 09:45:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 APR 2021

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

US3782162

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

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

Generated On: 10 Jun 2021 09:45:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	9 APR 2021
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Collection time (00:00-23:59)	10:47 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	9 APR 2021 10:47
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US3782162

Folder: Visit 4 Day 209 (1)

Form: Continuing

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

Generated On: 10 Jun 2021 09:45:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782162

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3782162

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:45:13

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3782162

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

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3782162

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 01:21:23

Generated On: 10 Jun 2021 09:45:13

Date of updated informed consent (dd MMM yyyy) 8 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 8 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3782162

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:30:02

Generated On: 10 Jun 2021 09:45:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 JAN 2021

Collection time (00:00-23:59)

09:57 (24 HR)

Collection date and time (derived)

8 JAN 2021 09:57

US3782162

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Jan 2021 20:30:02

Generated On: 10 Jun 2021 09:45:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 JAN 2021
Collection time (00:00 - 23:59)	09:59
Collection Date and Time (derived)	8 JAN 2021 09:59

US3782162

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Jan 2021 20:30:02

Generated On: 10 Jun 2021 09:45:13

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 01:21:22

Generated On: 10 Jun 2021 09:45:13

AEID	USA-US125-2020-MRNA-1273-P30 1000001
Adverse event	ACUTE CORONARY SYNDROME
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	21 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	21 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	24 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 01:21:22

Generated On: 10 Jun 2021 09:45:13

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	5 MINUTES OF CHEST PAIN ONLY BUT WENT TO HOSPITAL DUE TO HX OF CAD/CABG. TROPONIN, EKG, D-DIMER ALL NEGATIVE. LHC WITH PATENT STENTS AND STABLE CORONARY ANATOMY.

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 01:21:22

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 01:21:22

Generated On: 10 Jun 2021 09:45:13

AEID	USA-US125-2020-MRNA-1273-P30 1000004
Adverse event	CARDIAC CHEST PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 01:21:22

Generated On: 10 Jun 2021 09:45:13

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PARTICIPANT STATED ON SAFETY CALL THAT HE HAD A SMALL EPISODE OF CHEST PAIN. TOOK NITROGLYCERIN AND CHEST PAIN RESOLVED. (b) (6) IS FOLLOWING UP WITH HIS CARDIOLOGIST THIS WEEK.

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 01:21:22

Generated On: 10 Jun 2021 09:45:13

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)	

US3782162

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 01:21:22

Generated On: 10 Jun 2021 09:45:13

AEID	USA-US125-2021-MRNA-1273-P30 1000001
Adverse event	CARDIAC CHEST PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	21 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	23 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 01:21:22

Generated On: 10 Jun 2021 09:45:13

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 01:21:22

Generated On: 10 Jun 2021 09:45:13

PARTICIPANT ENTERED IN HIS
E DIARY ON DAY 138 THAT HE
HAD CONTACT WITH HIS
HEALTHCARE PROVIDER SINCE
THE LAST TIME HE HAD
COMPLETED HIS
QUESTIONNAIRE. CALL TO
PARTICIPANT. PARTICIPANT'S
WIFE ANSWERED THE PHONE
AND SHARED BRIEF DETAILS
ABOUT PARTICIPANT'S
CHANGE IN HEALTH. SHE
REPORTS ON THE NIGHT OF
21JAN2021 PARTICIPANT
BEGAN HAVING EPISODES OF
CHEST PAIN. HIS WIFE
REPORTS THAT PARTICIPANT
HAD CHEST PAIN THAT WAS
UNRELIEVED BY THREE DOSES
OF NITROGLYCERIN. HE WAS
ADMITTED TO THE HOSPITAL
YESTERDAY EVENING AND A
WORKUP IS IN PROGRESS. SHE
REPORTS THAT THE
PARTICIPANT DID NOT HAVE A
HEART ATTACK AND HE IS
CURRENTLY STABLE. WILL
PLAN FOLLOW-UP WITH
PARTICIPANT EARLY NEXT
WEEK.

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 01:21:22

Generated On: 10 Jun 2021 09:45:13

AEID	
Adverse event	MELANOMA RIGHT ARM
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 01:21:22

Generated On: 10 Jun 2021 09:45:13

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Jan 2021 20:30:02

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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

Generated On: 10 Jun 2021 09:45:13

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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

Generated On: 10 Jun 2021 09:45:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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

Generated On: 10 Jun 2021 09:45:13

Name of Medication ASA

Prophylaxis Yes ☐
No ☒

Indication CAD

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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

Generated On: 10 Jun 2021 09:45:13

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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

Generated On: 10 Jun 2021 09:45:13

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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

Generated On: 10 Jun 2021 09:45:13

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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

Generated On: 10 Jun 2021 09:45:13

Name of Medication CARBIDOPA/LEVODOPA

Prophylaxis Yes ☐
No ☒

Indication TREMORS

Dose per administration 25/100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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

Generated On: 10 Jun 2021 09:45:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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

Generated On: 10 Jun 2021 09:45:13

Name of Medication MIRALAX

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 17

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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

Generated On: 10 Jun 2021 09:45:13

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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

Generated On: 10 Jun 2021 09:45:13

Name of Medication FINASTERIDE

Prophylaxis Yes ☐
No ☒

Indication BPH

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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

Generated On: 10 Jun 2021 09:45:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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

Generated On: 10 Jun 2021 09:45:13

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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

Generated On: 10 Jun 2021 09:45:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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

Generated On: 10 Jun 2021 09:45:13

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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

Generated On: 10 Jun 2021 09:45:13

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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

Generated On: 10 Jun 2021 09:45:13

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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

Generated On: 10 Jun 2021 09:45:13

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

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

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Name of Medication PRIMIDONE

Prophylaxis Yes ☐
No ☒

Indication TREMOR

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

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

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

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

Generated On: 10 Jun 2021 09:45:13

Name of Medication FLOMAX

Prophylaxis Yes ☐
No ☒

Indication BPH

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

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

Generated On: 10 Jun 2021 09:45:13

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

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

Generated On: 10 Jun 2021 09:45:13

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 5,000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

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

Generated On: 10 Jun 2021 09:45:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

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

Generated On: 10 Jun 2021 09:45:13

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 ☐

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Form: Prior/Concomitant Medication and Vaccination (14)

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

Generated On: 10 Jun 2021 09:45:13

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

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

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Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

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

Generated On: 10 Jun 2021 09:45:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

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

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Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☒
No ☐

Indication POST-VACCINATION SYMPTOM
PROPHYLAXIS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

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

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		9 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

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

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Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐
No ☒

Indication CARDIAC CHEST PAIN

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

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

Generated On: 10 Jun 2021 09:45:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 14 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

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

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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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

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

Generated On: 10 Jun 2021 09:45:13

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

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

Generated On: 10 Jun 2021 09:45:13

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication CORNARY ARTERY DISEASE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

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

Generated On: 10 Jun 2021 09:45:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

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

Generated On: 10 Jun 2021 09:45:13

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐
No ☒

Indication CHEST PAIN (CARDIAC)

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

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

Generated On: 10 Jun 2021 09:45:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

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

Generated On: 10 Jun 2021 09:45:13

Name of Medication IMDUR

Prophylaxis Yes ☐
No ☒

Indication ANGINA

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

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

Generated On: 10 Jun 2021 09:45:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

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

Generated On: 10 Jun 2021 09:45:13

Name of Medication RANEXA

Prophylaxis Yes ☐
No ☒

Indication ANGINA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

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

Generated On: 10 Jun 2021 09:45:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

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

Generated On: 10 Jun 2021 09:45:13

Name of Medication ZOLEDRONIC ACID/PLACEBO

Prophylaxis Yes ☒
No ☐

Indication FRACTURE PROPHYLAXIS

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

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

Generated On: 10 Jun 2021 09:45:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	20 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

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

Generated On: 10 Jun 2021 09:45:13

Name of Medication GENERAL ANESTHESIA

Prophylaxis Yes ☐
No ☒

Indication R. ARM WIDE EXCISION OF
MELANOMA AND R. AXILLA
SENTINEL LYMPH NODE
BIOPSY

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

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

Generated On: 10 Jun 2021 09:45:13

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

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

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

Generated On: 10 Jun 2021 09:45:13

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication R. ARM WIDE EXCISION OF
MELANOMA AND R. AXILLA
SENTINEL LYMPH NODE
BIOPSY

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 21:43:21

Generated On: 10 Jun 2021 09:45:13

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	04 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 21:43:21

Generated On: 10 Jun 2021 09:45:13

Name of Medication HEPARIN

Prophylaxis Yes ☒
No ☐

Indication DVT PROPHYLAXIS

Dose per administration 5000

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNITS

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 21:43:21

Generated On: 10 Jun 2021 09:45:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	2 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 2 APR 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 21:43:21

Generated On: 10 Jun 2021 09:45:13

Name of Medication CEFAZOLIN

Prophylaxis Yes ☒
No ☐

Indication INFECTION PROPHYLAXIS

Dose per administration 2

Dose unit mg ☐
ug ☐
mL ☐
g ☒
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 21:43:21

Generated On: 10 Jun 2021 09:45:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	2 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 2 APR 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 28 Apr 2021 21:43:21

Generated On: 10 Jun 2021 09:45:13

Name of Medication ZOFRAN

Prophylaxis Yes ☒
No ☐

Indication NAUSEA PROPHYLAXIS

Dose per administration 4

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 28 Apr 2021 21:43:21

Generated On: 10 Jun 2021 09:45:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	2 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 2 APR 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Jan 2021 20:30:02

Generated On: 10 Jun 2021 09:45:13

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 21:43:21

Generated On: 10 Jun 2021 09:45:13

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
23 SEP 2020	LEFT HEART CATHETERIZATION	Adverse Event	
22 SEP 2020	NUCLEAR STRESS TEST	Adverse Event	
22 OCT 2020	COLONOSCOPY	Other	ROUTINE
12 MAR 2021	SKIN BIOPSY RIGHT ARM	Adverse Event	
02 APR 2021	R. ARM WIDE EXCISION OF MELANOMA AND R. AXILLA LYMPH NODE BIOPSY	Adverse Event	

US3782162

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:45:13

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:45:13

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

SAEID	USA-US125-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

SAEID	USA-US125-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/OCT/2020 09:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

SAEID	USA-US125-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	21/OCT/2020 14:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

SAEID	USA-US125-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	27/OCT/2020 18:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

SAEID	USA-US125-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	03/NOV/2020 09:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

SAEID	USA-US125-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

SAEID	USA-US125-2020-MRNA-1273-P301000004
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	27/OCT/2020 08:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

SAEID	USA-US125-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Jan 2021 20:30:03

Generated On: 10 Jun 2021 09:45:13

SAEID	USA-US125-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	24/JAN/2021 21:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3782162 (Prod: Vanderbilt University Medical Center)

US3782162

Form: Participant Creation

Generated On: 10 Jun 2021 09:45:13

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'US3782162'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	08 Sep 2020 18:09:27

US3782162

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 18:23:34

US3782162

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 18:09:28

US3782162

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Clinic (Clinic)'	Jenna Caserta (b) (4)	08 Sep 2020 18:23:34

US3782162

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered 'SCRN'	System	08 Sep 2020 18:23:34

US3782162

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:13

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered (b) (6) 1941'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 18:09:29

US3782162

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:13

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '78'	Jenna Caserta (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:13

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered 'YEARS'	System	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:13

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered '78'	System	08 Sep 2020 18:24:45

US3782162

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:13

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Male (M)'	Jenna Caserta (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:13

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jenna Caserta (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:13

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'I'	Jenna Caserta (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:13

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:13

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:13

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:13

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:13

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:13

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:13

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:45:13

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:13

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '8 Sep 2020'	Jenna Caserta (b) (4)	08 Sep 2020 18:24:45

US3782162

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:13

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered 'Sep 2020'	System	08 Sep 2020 18:24:45

US3782162

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:13

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered '2020'	System	08 Sep 2020 18:24:45

US3782162

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:13

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Amendment 3 (3)'	Jenna Caserta (b) (4)	08 Sep 2020 18:24:45

US3782162

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:13

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 18:24:45

US3782162

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:13

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 18:24:45

US3782162

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:13

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 18:24:45

US3782162

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:13

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 18:24:45

US3782162

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:13

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 18:09:28

US3782162

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:45:13

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered 'I'	System	08 Sep 2020 18:25:39

US3782162

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:45:13

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 18:25:39

US3782162

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:45:13

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 18:31:38

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 19:04:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 19:04:57
Data point term sent to Coder	System	08 Sep 2020 19:04:16
User entered 'Hypertension'	Jenna Caserta (b) (4)	08 Sep 2020 19:03:21
	(b) (4)	

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:03:21

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'I'	Jenna Caserta (b) (4)	08 Sep 2020 19:03:21

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 19:03:21

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:13

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:03:21

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 19:03:21

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:13

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:03:21

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:03:21

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:03:21

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:45:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:03:21

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 19:04:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 19:04:57
Data point term sent to Coder	System	08 Sep 2020 19:04:16
User entered 'Coronary Artery Disease'	Jenna Caserta (b) (4)	08 Sep 2020 19:03:40

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:03:40

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'I'	Jenna Caserta (b) (4)	08 Sep 2020 19:03:40

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 19:03:40

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:13

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:03:40

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 19:03:40

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:13

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:03:40

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:03:40

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:03:40

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:45:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:03:40

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 19:04:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 19:04:56
Data point term sent to Coder	System	08 Sep 2020 19:04:16
User entered 'Back Pain'	Jenna Caserta (b) (4)	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'un UNK 2017'	Jenna Caserta (b) (4)	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:13

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:13

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered 'Jan 2017'	System	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered '2017'	System	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:45:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 19:06:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 19:06:50
Data point term sent to Coder	System	08 Sep 2020 19:05:20
User entered 'GERD'	Jenna Caserta (b) (4)	08 Sep 2020 19:04:31

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:04:31

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'I'	Jenna Caserta (b) (4)	08 Sep 2020 19:04:31

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 19:04:31

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:13

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:04:31

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 19:04:31

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:13

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:04:31

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:04:31

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:04:31

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:45:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:04:31

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: BPH - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 19:06:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 19:06:50
Data point term sent to Coder	System	08 Sep 2020 19:05:20
User entered 'BPH'	Jenna Caserta (b) (4)	08 Sep 2020 19:04:56

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'un UNK 2015'	Jenna Caserta (b) (4)	08 Sep 2020 19:04:56

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 19:04:56

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 19:04:56

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:13

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:04:56

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 19:04:56

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:13

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered 'Jan 2015'	System	08 Sep 2020 19:04:56

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered '2015'	System	08 Sep 2020 19:04:56

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:04:56

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:45:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:04:56

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Essential tremor, LLT: Essential tremor - version MedDRA\23.0.	Coder Import (b) (4)	27 Jan 2021 18:37:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Jan 2021 18:37:10
Data point term sent to Coder	System	27 Jan 2021 18:36:42
Coding entries removed.	Carlton Griffin (b) (4)	27 Jan 2021 18:36:28
Signature has been broken.	Carlton Griffin (b) (4)	27 Jan 2021 18:36:28
User entered 'Essential tremor' reason for change: New Information	Carlton Griffin (b) (4)	27 Jan 2021 18:36:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Parkinson's disease and parkinsonism, PT: Parkinson's disease, LLT: Parkinson's disease - version MedDRA\23.0.	Coder Import (b) (4)	26 Jan 2021 18:14:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Jan 2021 18:14:51
Data point term sent to Coder	System	26 Jan 2021 18:14:15
Coding entries removed.	Carlton Griffin (b) (4)	26 Jan 2021 18:14:04
User entered 'Parkinson's Disease' reason for change: New Information	Carlton Griffin (b) (4)	26 Jan 2021 18:14:04
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Tremor, LLT: Tremor - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 19:07:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 19:07:54
Data point term sent to Coder	System	08 Sep 2020 19:06:21
User entered 'Tremor'	Jenna Caserta (b) (4)	08 Sep 2020 19:05:21

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:05:21

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'I'	Jenna Caserta (b) (4)	08 Sep 2020 19:05:21

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 19:05:21

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:13

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:05:21

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 19:05:21

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:13

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:05:21

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:05:21

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:05:21

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:45:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:05:21

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	08 Sep 2020 19:07:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 19:07:55
Data point term sent to Coder	System	08 Sep 2020 19:06:21
User entered 'Hyperlipidemia'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:05:42

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:05:42

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'I'	Jenna Caserta (b) (4)	08 Sep 2020 19:05:42

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 19:05:42

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:13

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:05:42

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 19:05:42

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:13

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:05:42

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:05:42

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:05:42

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:45:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:05:42

US3782162

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness neurosensory, LLT: Sensory hearing loss - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 19:07:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 19:07:55
Data point term sent to Coder	System	08 Sep 2020 19:06:21
User entered 'Sensory Hearing Loss'	Jenna Caserta (b) (4)	08 Sep 2020 19:05:56

US3782162

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:05:56

US3782162

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'I'	Jenna Caserta (b) (4)	08 Sep 2020 19:05:56

US3782162

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 19:05:56

US3782162

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:13

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:05:56

US3782162

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 19:05:56

US3782162

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:13

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:05:56

US3782162

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:05:56

US3782162

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:05:56

US3782162

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:45:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:05:56

US3782162

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 19:07:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 19:07:55
Data point term sent to Coder	System	08 Sep 2020 19:07:22
User entered 'Constipation'	Jenna Caserta (b) (4)	08 Sep 2020 19:06:41
	(b) (4)	

US3782162

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:06:41

US3782162

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'I'	Jenna Caserta (b) (4)	08 Sep 2020 19:06:41

US3782162

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 19:06:41

US3782162

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:13

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:06:41

US3782162

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 19:06:41

US3782162

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:13

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:06:41

US3782162

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:06:41

US3782162

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:06:41

US3782162

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:45:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	08 Sep 2020 19:06:41

US3782162

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Angina pectoris - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 18:45:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 18:45:07
Data point term sent to Coder	System	27 Jan 2021 18:43:49
User entered 'angina'	Carlton Griffin (b) (4)	27 Jan 2021 18:43:17
DataPoint activated with code reason code Data required.	Carlton Griffin (b) (4)	27 Jan 2021 18:42:29
DataPoint inactivated with code reason code Data not required.	Carlton Griffin (b) (4)	26 Jan 2021 18:13:49

US3782162

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered '30 Oct 2017'	Carlton Griffin (b) (4)	27 Jan 2021 18:43:17
DataPoint activated with code reason code Data required.	Carlton Griffin (b) (4)	27 Jan 2021 18:42:29
DataPoint inactivated with code reason code Data not required.	Carlton Griffin (b) (4)	26 Jan 2021 18:13:49

US3782162

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered '0'	Carlton Griffin (b) (4)	27 Jan 2021 18:43:17
DataPoint activated with code reason code Data required.	Carlton Griffin (b) (4)	27 Jan 2021 18:42:29
DataPoint inactivated with code reason code Data not required.	Carlton Griffin (b) (4)	26 Jan 2021 18:13:49

US3782162

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	27 Jan 2021 18:43:17
DataPoint activated with code reason code Data required.	Carlton Griffin (b) (4)	27 Jan 2021 18:42:29
DataPoint inactivated with code reason code Data not required.	Carlton Griffin (b) (4)	26 Jan 2021 18:13:49

US3782162

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:13

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered empty.	(b) (4)	
	Carlton Griffin (b) (4)	27 Jan 2021 18:43:17
	(b) (4)	
DataPoint activated with code reason code Data required.	Carlton Griffin (b) (4)	27 Jan 2021 18:42:29
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Carlton Griffin (b) (4)	26 Jan 2021 18:13:49
	(b) (4)	

US3782162

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered '0'	Carlton Griffin (b) (4)	27 Jan 2021 18:43:17
DataPoint activated with code reason code Data required.	Carlton Griffin (b) (4)	27 Jan 2021 18:42:29
DataPoint inactivated with code reason code Data not required.	Carlton Griffin (b) (4)	26 Jan 2021 18:13:49

US3782162

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:13

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered 'Oct 2017'	System	27 Jan 2021 18:43:17
DataPoint activated with code reason code Data required.	Carlton Griffin (b) (4)	27 Jan 2021 18:42:29
DataPoint inactivated with code reason code Data not required.	Carlton Griffin (b) (4)	26 Jan 2021 18:13:49

US3782162

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:13

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered '2017'	System	27 Jan 2021 18:43:17
DataPoint activated with code reason code Data required.	Carlton Griffin (b) (4)	27 Jan 2021 18:42:29
DataPoint inactivated with code reason code Data not required.	Carlton Griffin (b) (4)	26 Jan 2021 18:13:49

US3782162

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:13

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	27 Jan 2021 18:43:17
DataPoint activated with code reason code Data required.	Carlton Griffin (b) (4)	27 Jan 2021 18:42:29
DataPoint inactivated with code reason code Data not required.	Carlton Griffin (b) (4)	26 Jan 2021 18:13:49

US3782162

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:45:13

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered empty.	System	27 Jan 2021 18:43:17
DataPoint activated with code reason code Data required.	Carlton Griffin (b) (4)	27 Jan 2021 18:42:29
DataPoint inactivated with code reason code Data not required.	Carlton Griffin (b) (4)	26 Jan 2021 18:13:49

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '8 Sep 2020'	Jenna Caserta (b) (4)	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '13:06'	Jenna Caserta (b) (4)	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered '8 Sep 2020 13:06'	System	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '161.5' cm	Jenna Caserta (b) (4)	08 Sep 2020 18:45:55
DataPoint set to visible.	System	08 Sep 2020 18:25:39

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '76.9' kg	Jenna Caserta (b) (4)	08 Sep 2020 18:45:55
DataPoint set to visible.	System	08 Sep 2020 18:25:39

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered '29.48365'	System	08 Sep 2020 18:45:55
DataPoint set to visible.	System	08 Sep 2020 18:25:39

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered 'kg/m2'	System	08 Sep 2020 18:45:55
DataPoint set to visible.	System	08 Sep 2020 18:25:39

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered missing code ND - Not Done.	Jenna Caserta (b) (4)	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User closed query 'Data is required please update accordingly.' (Site from DM).	(b) (4)	
Query 'Data is required please update accordingly.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 17:52:33
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 16:10:10
User opened query 'Data is required please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 16:09:52
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 11:36:30
	Jenna Caserta (b) (4)	08 Sep 2020 18:45:55
	(b) (4)	

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered missing code ND - Not Done.	Jenna Caserta (b) (4)	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered 'bpm'	System	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered missing code ND - Not Done.	Jenna Caserta (b) (4)	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered 'breaths/min'	System	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered missing code ND - Not Done.	Jenna Caserta (b) (4)	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered 'mmHg'	System	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered missing code ND - Not Done.	Jenna Caserta (b) (4)	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User entered 'mmHg'	System	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32

US3782162

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 18:32:30

US3782162

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '8 Sep 2020'	Jenna Caserta (b) (4)	08 Sep 2020 18:32:30

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:13

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:13

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

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Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:13

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:13

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

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Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

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Folder: Screening

Form: Risk of Exposure

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Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

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Folder: Screening

Form: Risk of Exposure

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

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Folder: Screening

Form: Risk of Exposure

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

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Folder: Screening

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:13

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:13

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:13

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:13

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:13

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'I'	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:13

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:45:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 18:25:24

US3782162

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 13:21:33
User entered '8 Sep 2020'	Jenna Caserta (b) (4)	08 Sep 2020 18:25:24

US3782162

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Clinic (Clinic)'	Jenna Caserta (b) (4)	08 Sep 2020 18:25:24

US3782162

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'VISIT1'	System	08 Sep 2020 18:25:24

US3782162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:13

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 18:19:59

US3782162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:13

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '190005'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 18:19:59

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:13

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 18:19:59

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:13

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 18:33:17

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:13

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 18:33:17

US3782162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:13

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 18:33:17

US3782162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:13

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 18:33:17

US3782162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:13

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 18:33:17

US3782162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:45:13

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:41:53
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:41:14
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:41:12

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered missing code ND - Not Done.	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered missing code ND - Not Done.	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered missing code ND - Not Done.	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered missing code ND - Not Done.	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User accepted default value 'Pre-Dose (PREDOSE)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:33:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 13:23:13
User entered '8 Sep 2020'	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '13:06'	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered '08 Sep 2020 13:06'	System	10 Nov 2020 13:23:13
User entered '8 Sep 2020 13:06'	System	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '37.0' C	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Oral (Oral)'	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '98'	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'bpm'	System	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '16'	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'breaths/min'	System	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '141'	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'mmHg'	System	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:59:14
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Carlton Griffin (b) (4) (b) (4)	17 Sep 2020 18:22:32
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:30:31
User entered '59'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'mmHg'	System	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered missing code ND - Not Done.	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:45:13

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered missing code ND - Not Done.	(b) (4) Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User accepted default value 'Post-Dose (POSTDOSE)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 13:23:13
User entered '8 Sep 2020'	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35
	(b) (4)	

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '14:13'	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered '08 Sep 2020 14:13'	System	10 Nov 2020 13:23:13
User entered '8 Sep 2020 14:13'	System	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '97.8' F	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Oral (Oral)'	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '81'	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'bpm'	System	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '18'	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'breaths/min'	System	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '123'	Jenna Caserta (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'mmHg'	System	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:59:05
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Carlton Griffin (b) (4) (b) (4)	17 Sep 2020 18:22:42
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:30:31
User entered '57'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'mmHg'	System	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 18:47:27

US3782162

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 18:47:27

US3782162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 18:49:13

US3782162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 18:49:13

US3782162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 18:49:13

US3782162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 18:49:13

US3782162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 13:21:53
User entered '8 Sep 2020'	Jenna Caserta (b) (4)	08 Sep 2020 18:49:13
	(b) (4)	

US3782162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '13:43'	Jenna Caserta (b) (4)	08 Sep 2020 18:49:13

US3782162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered '08 Sep 2020 13:43'	System	10 Nov 2020 13:21:53
User entered '8 Sep 2020 13:43'	System	08 Sep 2020 18:49:13

US3782162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Left Arm (LEFT ARM)'	Jenna Caserta (b) (4)	08 Sep 2020 18:49:13

US3782162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'ONCE'	System	08 Sep 2020 18:49:13

US3782162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 18:49:13

US3782162

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 18:46:54

US3782162

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 13:22:03
User entered '8 Sep 2020'	Jenna Caserta (b) (4)	08 Sep 2020 18:46:54
	(b) (4)	

US3782162

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '13:18'	Jenna Caserta (b) (4)	08 Sep 2020 18:46:54

US3782162

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered '08 Sep 2020 13:18'	System	10 Nov 2020 13:22:03
User entered '8 Sep 2020 13:18'	System	08 Sep 2020 18:46:54

US3782162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:45:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 13:22:11
User entered '8 Sep 2020'	Jenna Caserta (b) (4)	08 Sep 2020 18:47:08
	(b) (4)	

US3782162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:47:08

US3782162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 18:47:08

US3782162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '13:21'	Jenna Caserta (b) (4)	08 Sep 2020 18:47:08

US3782162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered '08 Sep 2020 13:21'	System	10 Nov 2020 13:22:11
User entered '8 Sep 2020 13:21'	System	08 Sep 2020 18:47:08

US3782162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:47:08

US3782162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 18:47:08

US3782162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 18:47:08

US3782162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered empty.	System	08 Sep 2020 18:47:08

US3782162

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 18:47:53

US3782162

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'I'	System	08 Sep 2020 18:47:53

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T14:15:49', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '24eb2efd-bfd3-4c9e-a988-fd0617775116'	System	08 Sep 2020 19:17:06
User entered 'Yes (Y)'	System	08 Sep 2020 19:17:06

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T14:16:05', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '24eb2efd-bfd3-4c9e-a988-fd0617775116'	System	08 Sep 2020 19:17:06
User entered '97.8'	System	08 Sep 2020 19:17:06

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T14:16:45', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '24eb2efd-bfd3-4c9e-a988-fd0617775116'	System	08 Sep 2020 19:17:06
User entered 'No (N)'	System	08 Sep 2020 19:17:06

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T14:17:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '24eb2efd-bfd3-4c9e-a988-fd0617775116'	System	08 Sep 2020 19:17:06
User entered '08 Sep 2020 14:17'	System	08 Sep 2020 19:17:06

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '08 Sep 2020 14:03'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '08 Sep 2020 16:33'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T18:45:23', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '071bbaa0-9ac7-478c-86a6-6268f8a88732'	System	08 Sep 2020 23:46:11
User entered 'Yes (Y)'	System	08 Sep 2020 23:46:11

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T18:45:36', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '071bbaa0-9ac7-478c-86a6-6268f8a88732'	System	08 Sep 2020 23:46:11
User entered '97.2'	System	08 Sep 2020 23:46:11

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T18:45:44', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '071bbaa0-9ac7-478c-86a6-6268f8a88732'	System	08 Sep 2020 23:46:11
User entered 'No (N)'	System	08 Sep 2020 23:46:11

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T18:46:04', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '071bbaa0-9ac7-478c-86a6-6268f8a88732'	System	08 Sep 2020 23:46:11
User entered '08 Sep 2020 18:46'	System	08 Sep 2020 23:46:11

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '08 Sep 2020 17:28'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 2'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-09T19:14:42', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ded8b307-d043-45be-a962-e24568b00a45'	System	10 Sep 2020 00:15:15
User entered 'Yes (Y)'	System	10 Sep 2020 00:15:15

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-09T19:14:56', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ded8b307-d043-45be-a962-e24568b00a45'	System	10 Sep 2020 00:15:15
User entered '99.7'	System	10 Sep 2020 00:15:15

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-09T19:15:03', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ded8b307-d043-45be-a962-e24568b00a45'	System	10 Sep 2020 00:15:15
User entered 'No (N)'	System	10 Sep 2020 00:15:15

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-09T19:15:10', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ded8b307-d043-45be-a962-e24568b00a45'	System	10 Sep 2020 00:15:15
User entered '09 Sep 2020 19:15'	System	10 Sep 2020 00:15:15

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 3'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-10T17:51:34', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '731e0ae5-c424-4724-a211-9814bfaf722f'	System	10 Sep 2020 22:52:04
User entered 'Yes (Y)'	System	10 Sep 2020 22:52:04

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-10T17:51:41', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '731e0ae5-c424-4724-a211-9814bfaf722f' User entered '97.2'	System	10 Sep 2020 22:52:04
	System	10 Sep 2020 22:52:04

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-10T17:51:49', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '731e0ae5-c424-4724-a211-9814bfaf722f'	System	10 Sep 2020 22:52:04
User entered 'No (N)'	System	10 Sep 2020 22:52:04

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-10T17:51:59', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '731e0ae5-c424-4724-a211-9814bfaf722f' User entered '10 Sep 2020 17:51'	System	10 Sep 2020 22:52:04
	System	10 Sep 2020 22:52:04

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 4'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-11T18:55:18', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '3e890533-b838-4ad9-ba46-4c6e7b05c594'	System	11 Sep 2020 23:56:00
User entered 'Yes (Y)'	System	11 Sep 2020 23:56:00

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-11T18:55:38', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '3e890533-b838-4ad9-ba46-4c6e7b05c594'	System	11 Sep 2020 23:56:00
User entered '97.2'	System	11 Sep 2020 23:56:00

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-11T18:55:44', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '3e890533-b838-4ad9-ba46-4c6e7b05c594'	System	11 Sep 2020 23:56:00
User entered 'No (N)'	System	11 Sep 2020 23:56:00

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-11T18:55:55', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '3e890533-b838-4ad9-ba46-4c6e7b05c594'	System	11 Sep 2020 23:56:00
User entered '11 Sep 2020 18:55'	System	11 Sep 2020 23:56:00

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 5'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T08:11:37', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '3e78b21d-50ac-4fa8-8628-35ba155028ba'	System	13 Sep 2020 13:12:08
User entered 'Yes (Y)'	System	13 Sep 2020 13:12:08

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T08:11:50', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '3e78b21d-50ac-4fa8-8628-35ba155028ba' User entered '97.6'	System	13 Sep 2020 13:12:08
	System	13 Sep 2020 13:12:08

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T08:11:55', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '3e78b21d-50ac-4fa8-8628-35ba155028ba'	System	13 Sep 2020 13:12:08
User entered 'No (N)'	System	13 Sep 2020 13:12:08

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T08:12:05', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '3e78b21d-50ac-4fa8-8628-35ba155028ba'	System	13 Sep 2020 13:12:08
User entered '13 Sep 2020 08:12'	System	13 Sep 2020 13:12:08

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 6'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T21:24:53', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '94e93564-9903-4b7f-b781-c5828e1ac4f5'	System	14 Sep 2020 02:25:01
User entered 'Yes (Y)'	System	14 Sep 2020 02:25:01

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T21:24:38', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '94e93564-9903-4b7f-b781-c5828e1ac4f5'	System	14 Sep 2020 02:25:01
User entered '98.6'	System	14 Sep 2020 02:25:01

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T21:24:42', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '94e93564-9903-4b7f-b781-c5828e1ac4f5'	System	14 Sep 2020 02:25:01
User entered 'No (N)'	System	14 Sep 2020 02:25:01

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T21:24:57', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '94e93564-9903-4b7f-b781-c5828e1ac4f5'	System	14 Sep 2020 02:25:01
User entered '13 Sep 2020 21:24'	System	14 Sep 2020 02:25:01

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 7'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-14T19:40:58', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '70f4780a-511f-4087-9115-82ad9eb924ff'	System	15 Sep 2020 00:41:33
User entered 'Yes (Y)'	System	15 Sep 2020 00:41:33

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-14T19:41:16', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '70f4780a-511f-4087-9115-82ad9eb924ff'	System	15 Sep 2020 00:41:33
User entered '97.7'	System	15 Sep 2020 00:41:33

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-14T19:41:24', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '70f4780a-511f-4087-9115-82ad9eb924ff'	System	15 Sep 2020 00:41:33
User entered 'No (N)'	System	15 Sep 2020 00:41:33

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-14T19:41:29', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '70f4780a-511f-4087-9115-82ad9eb924ff'	System	15 Sep 2020 00:41:33
User entered '14 Sep 2020 19:41'	System	15 Sep 2020 00:41:33

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T14:17:29', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '6f138f97-fb79-4319-a300-3ce1c52d1093'	System	08 Sep 2020 19:18:07
User entered 'None (1)'	System	08 Sep 2020 19:18:07

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T14:17:43', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '6f138f97-fb79-4319-a300-3ce1c52d1093'	System	08 Sep 2020 19:18:07
User entered 'No (N)'	System	08 Sep 2020 19:18:07

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T14:17:47', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '6f138f97-fb79-4319-a300-3ce1c52d1093'	System	08 Sep 2020 19:18:07
User entered 'No (N)'	System	08 Sep 2020 19:18:07

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T14:17:56', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '6f138f97-fb79-4319-a300-3ce1c52d1093'	System	08 Sep 2020 19:18:07
User entered 'None (1)'	System	08 Sep 2020 19:18:07

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T14:18:03', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '6f138f97-fb79-4319-a300-3ce1c52d1093'	System	08 Sep 2020 19:18:07
User entered '08 Sep 2020 14:18'	System	08 Sep 2020 19:18:07

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '08 Sep 2020 14:03'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '08 Sep 2020 16:33'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T18:46:24', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'bb4c65a3-fc39-4b41-a50d-28a059661650'	System	08 Sep 2020 23:47:04
User entered 'None (1)'	System	08 Sep 2020 23:47:04

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T18:46:36', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'bb4c65a3-fc39-4b41-a50d-28a059661650'	System	08 Sep 2020 23:47:04
User entered 'No (N)'	System	08 Sep 2020 23:47:04

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T18:46:44', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'bb4c65a3-fc39-4b41-a50d-28a059661650'	System	08 Sep 2020 23:47:04
User entered 'No (N)'	System	08 Sep 2020 23:47:04

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T18:46:52', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'bb4c65a3-fc39-4b41-a50d-28a059661650'	System	08 Sep 2020 23:47:04
User entered 'None (1)'	System	08 Sep 2020 23:47:04

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T18:47:01', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'bb4c65a3-fc39-4b41-a50d-28a059661650'	System	08 Sep 2020 23:47:04
User entered '08 Sep 2020 18:47'	System	08 Sep 2020 23:47:04

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '08 Sep 2020 17:28'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 2'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-09T19:15:22', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f2a86eda-9270-4784-b391-5abcad53a25f'	System	10 Sep 2020 00:16:37
User entered 'None (1)'	System	10 Sep 2020 00:16:37

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:13

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-09T19:15:38', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f2a86eda-9270-4784-b391-5abcad53a25f'	System	10 Sep 2020 00:16:37
User entered 'No (N)'	System	10 Sep 2020 00:16:37

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-09T19:16:08', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f2a86eda-9270-4784-b391-5abcad53a25f'	System	10 Sep 2020 00:16:37
User entered 'No (N)'	System	10 Sep 2020 00:16:37

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-09T19:16:13', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f2a86eda-9270-4784-b391-5abcad53a25f'	System	10 Sep 2020 00:16:37
User entered 'None (1)'	System	10 Sep 2020 00:16:37

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-09T19:16:31', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f2a86eda-9270-4784-b391-5abcad53a25f' User entered '09 Sep 2020 19:16'	System	10 Sep 2020 00:16:37
	System	10 Sep 2020 00:16:37

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 3'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-10T17:52:09', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '9a811a50-fa34-4618-914e-2fca01cbda85'	System	10 Sep 2020 22:52:39
User entered 'None (1)'	System	10 Sep 2020 22:52:39

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-10T17:52:15', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '9a811a50-fa34-4618-914e-2fca01cbda85'	System	10 Sep 2020 22:52:39
User entered 'No (N)'	System	10 Sep 2020 22:52:39

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-10T17:52:19', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '9a811a50-fa34-4618-914e-2fca01cbda85'	System	10 Sep 2020 22:52:39
User entered 'No (N)'	System	10 Sep 2020 22:52:39

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-10T17:52:24', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '9a811a50-fa34-4618-914e-2fca01cbda85'	System	10 Sep 2020 22:52:39
User entered 'None (1)'	System	10 Sep 2020 22:52:39

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-10T17:52:34', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '9a811a50-fa34-4618-914e-2fca01cbda85'	System	10 Sep 2020 22:52:39
User entered '10 Sep 2020 17:52'	System	10 Sep 2020 22:52:39

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 4'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-11T18:56:09', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '90662eaa-7022-4add-9db5-5f90b25ce82f'	System	11 Sep 2020 23:56:34
User entered 'None (1)'	System	11 Sep 2020 23:56:34

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-11T18:56:14', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '90662eaa-7022-4add-9db5-5f90b25ce82f'	System	11 Sep 2020 23:56:34
User entered 'No (N)'	System	11 Sep 2020 23:56:34

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-11T18:56:18', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '90662eaa-7022-4add-9db5-5f90b25ce82f'	System	11 Sep 2020 23:56:34
User entered 'No (N)'	System	11 Sep 2020 23:56:34

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-11T18:56:24', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '90662eaa-7022-4add-9db5-5f90b25ce82f'	System	11 Sep 2020 23:56:34
User entered 'None (1)'	System	11 Sep 2020 23:56:34

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-11T18:56:31', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '90662eaa-7022-4add-9db5-5f90b25ce82f'	System	11 Sep 2020 23:56:34
User entered '11 Sep 2020 18:56'	System	11 Sep 2020 23:56:34

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 5'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T08:12:12', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '12c048da-1000-4a81-be81-9b87aaf046e5'	System	13 Sep 2020 13:12:31
User entered 'None (1)'	System	13 Sep 2020 13:12:31

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T08:12:15', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '12c048da-1000-4a81-be81-9b87aaf046e5'	System	13 Sep 2020 13:12:31
User entered 'No (N)'	System	13 Sep 2020 13:12:31

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T08:12:20', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '12c048da-1000-4a81-be81-9b87aaf046e5'	System	13 Sep 2020 13:12:31
User entered 'No (N)'	System	13 Sep 2020 13:12:31

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T08:12:24', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '12c048da-1000-4a81-be81-9b87aaf046e5'	System	13 Sep 2020 13:12:31
User entered 'None (1)'	System	13 Sep 2020 13:12:31

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T08:12:27', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '12c048da-1000-4a81-be81-9b87aaf046e5'	System	13 Sep 2020 13:12:31
User entered '13 Sep 2020 08:12'	System	13 Sep 2020 13:12:31

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 6'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T21:25:04', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'c10627b4-1384-4e9f-8dd7-c864f61a8dd9'	System	14 Sep 2020 02:25:31
User entered 'None (1)'	System	14 Sep 2020 02:25:31

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T21:25:10', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'c10627b4-1384-4e9f-8dd7-c864f61a8dd9'	System	14 Sep 2020 02:25:31
User entered 'No (N)'	System	14 Sep 2020 02:25:31

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T21:25:14', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'c10627b4-1384-4e9f-8dd7-c864f61a8dd9'	System	14 Sep 2020 02:25:31
User entered 'No (N)'	System	14 Sep 2020 02:25:31

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T21:25:22', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'c10627b4-1384-4e9f-8dd7-c864f61a8dd9'	System	14 Sep 2020 02:25:31
User entered 'None (1)'	System	14 Sep 2020 02:25:31

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T21:25:28', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'c10627b4-1384-4e9f-8dd7-c864f61a8dd9'	System	14 Sep 2020 02:25:31
User entered '13 Sep 2020 21:25'	System	14 Sep 2020 02:25:31

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 7'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-14T19:41:35', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '8b83e1ac-8eef-466e-9ff8-a8248bf7475c'	System	15 Sep 2020 00:41:57
User entered 'None (1)'	System	15 Sep 2020 00:41:57

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:13

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-14T19:41:39', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '8b83e1ac-8eef-466e-9ff8-a8248bf7475c'	System	15 Sep 2020 00:41:57
User entered 'No (N)'	System	15 Sep 2020 00:41:57

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-14T19:41:42', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '8b83e1ac-8eef-466e-9ff8-a8248bf7475c'	System	15 Sep 2020 00:41:57
User entered 'No (N)'	System	15 Sep 2020 00:41:57

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-14T19:41:47', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '8b83e1ac-8eef-466e-9ff8-a8248bf7475c'	System	15 Sep 2020 00:41:57
User entered 'None (1)'	System	15 Sep 2020 00:41:57

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-14T19:41:52', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '8b83e1ac-8eef-466e-9ff8-a8248bf7475c'	System	15 Sep 2020 00:41:57
User entered '14 Sep 2020 19:41'	System	15 Sep 2020 00:41:57

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T14:18:14', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ed9aadd0-3a9b-4656-badf-a17edc676927'	System	08 Sep 2020 19:18:55
User entered 'None (0)'	System	08 Sep 2020 19:18:55

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T14:18:18', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ed9aadd0-3a9b-4656-badf-a17edc676927'	System	08 Sep 2020 19:18:55
User entered 'None (0)'	System	08 Sep 2020 19:18:55

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T14:18:22', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ed9aadd0-3a9b-4656-badf-a17edc676927'	System	08 Sep 2020 19:18:55
User entered 'None (0)'	System	08 Sep 2020 19:18:55

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T14:18:26', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ed9aadd0-3a9b-4656-badf-a17edc676927'	System	08 Sep 2020 19:18:55
User entered 'None (0)'	System	08 Sep 2020 19:18:55

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T14:18:29', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ed9aadd0-3a9b-4656-badf-a17edc676927'	System	08 Sep 2020 19:18:55
User entered 'None (0)'	System	08 Sep 2020 19:18:55

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T14:18:34', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ed9aadd0-3a9b-4656-badf-a17edc676927'	System	08 Sep 2020 19:18:55
User entered 'None (0)'	System	08 Sep 2020 19:18:55

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T14:18:46', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ed9aadd0-3a9b-4656-badf-a17edc676927'	System	08 Sep 2020 19:18:55
User entered 'No (N)'	System	08 Sep 2020 19:18:55

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T14:18:50', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ed9aadd0-3a9b-4656-badf-a17edc676927'	System	08 Sep 2020 19:18:55
User entered '08 Sep 2020 14:18'	System	08 Sep 2020 19:18:55

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '08 Sep 2020 14:03'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '08 Sep 2020 16:33'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T18:47:18', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'e65f74d1-06eb-4153-9eb9-b11c64179b7e' User entered 'None (0)'	System	08 Sep 2020 23:48:17
	System	08 Sep 2020 23:48:17

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T18:47:27', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'e65f74d1-06eb-4153-9eb9-b11c64179b7e'	System	08 Sep 2020 23:48:17
User entered 'Some interference with activity (2)'	System	08 Sep 2020 23:48:17

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T18:47:36', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'e65f74d1-06eb-4153-9eb9-b11c64179b7e'	System	08 Sep 2020 23:48:17
User entered 'None (0)'	System	08 Sep 2020 23:48:17

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T18:47:45', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'e65f74d1-06eb-4153-9eb9-b11c64179b7e' User entered 'None (0)'	System	08 Sep 2020 23:48:17
	System	08 Sep 2020 23:48:17

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T18:47:49', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'e65f74d1-06eb-4153-9eb9-b11c64179b7e'	System	08 Sep 2020 23:48:17
User entered 'None (0)'	System	08 Sep 2020 23:48:17

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T18:47:52', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'e65f74d1-06eb-4153-9eb9-b11c64179b7e' User entered 'None (0)'	System	08 Sep 2020 23:48:17
	System	08 Sep 2020 23:48:17

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T18:47:59', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'e65f74d1-06eb-4153-9eb9-b11c64179b7e'	System	08 Sep 2020 23:48:17
User entered 'No (N)'	System	08 Sep 2020 23:48:17

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-08T18:48:14', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'e65f74d1-06eb-4153-9eb9-b11c64179b7e'	System	08 Sep 2020 23:48:17
User entered '08 Sep 2020 18:48'	System	08 Sep 2020 23:48:17

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '08 Sep 2020 17:28'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 2'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-09T19:16:41', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0bef0e91-9e23-413f-af19-b536f3075342'	System	10 Sep 2020 00:17:14
User entered 'None (0)'	System	10 Sep 2020 00:17:14

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-09T19:16:46', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0bef0e91-9e23-413f-af19-b536f3075342'	System	10 Sep 2020 00:17:14
User entered 'No interference with activity (1)'	System	10 Sep 2020 00:17:14

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-09T19:16:50', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0bef0e91-9e23-413f-af19-b536f3075342'	System	10 Sep 2020 00:17:14
User entered 'None (0)'	System	10 Sep 2020 00:17:14

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-09T19:16:53', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0bef0e91-9e23-413f-af19-b536f3075342'	System	10 Sep 2020 00:17:14
User entered 'None (0)'	System	10 Sep 2020 00:17:14

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-09T19:16:57', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0bef0e91-9e23-413f-af19-b536f3075342'	System	10 Sep 2020 00:17:14
User entered 'None (0)'	System	10 Sep 2020 00:17:14

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-09T19:17:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0bef0e91-9e23-413f-af19-b536f3075342'	System	10 Sep 2020 00:17:14
User entered 'None (0)'	System	10 Sep 2020 00:17:14

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-09T19:17:05', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0bef0e91-9e23-413f-af19-b536f3075342'	System	10 Sep 2020 00:17:14
User entered 'No (N)'	System	10 Sep 2020 00:17:14

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-09T19:17:11', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0bef0e91-9e23-413f-af19-b536f3075342'	System	10 Sep 2020 00:17:14
User entered '09 Sep 2020 19:17'	System	10 Sep 2020 00:17:14

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 3'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-10T17:52:41', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '130f0c4d-844e-4164-818e-9884339d0d65'	System	10 Sep 2020 22:53:35
User entered 'None (0)'	System	10 Sep 2020 22:53:35

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-10T17:52:51', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '130f0c4d-844e-4164-818e-9884339d0d65'	System	10 Sep 2020 22:53:35
User entered 'Some interference with activity (2)'	System	10 Sep 2020 22:53:35

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-10T17:53:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '130f0c4d-844e-4164-818e-9884339d0d65'	System	10 Sep 2020 22:53:35
User entered 'None (0)'	System	10 Sep 2020 22:53:35

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-10T17:53:04', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '130f0c4d-844e-4164-818e-9884339d0d65'	System	10 Sep 2020 22:53:35
User entered 'None (0)'	System	10 Sep 2020 22:53:35

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-10T17:53:07', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '130f0c4d-844e-4164-818e-9884339d0d65'	System	10 Sep 2020 22:53:35
User entered 'None (0)'	System	10 Sep 2020 22:53:35

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-10T17:53:10', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '130f0c4d-844e-4164-818e-9884339d0d65'	System	10 Sep 2020 22:53:35
User entered 'None (0)'	System	10 Sep 2020 22:53:35

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-10T17:53:20', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '130f0c4d-844e-4164-818e-9884339d0d65'	System	10 Sep 2020 22:53:35
User entered 'No (N)'	System	10 Sep 2020 22:53:35

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-10T17:53:30', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '130f0c4d-844e-4164-818e-9884339d0d65'	System	10 Sep 2020 22:53:35
User entered '10 Sep 2020 17:53'	System	10 Sep 2020 22:53:35

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 4'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-11T18:56:39', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '1c9db203-c636-491d-91c4-b294c4be2800'	System	11 Sep 2020 23:57:09
User entered 'None (0)'	System	11 Sep 2020 23:57:09

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-11T18:56:43', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '1c9db203-c636-491d-91c4-b294c4be2800'	System	11 Sep 2020 23:57:09
User entered 'None (0)'	System	11 Sep 2020 23:57:09

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-11T18:56:46', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '1c9db203-c636-491d-91c4-b294c4be2800'	System	11 Sep 2020 23:57:09
User entered 'None (0)'	System	11 Sep 2020 23:57:09

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-11T18:56:49', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '1c9db203-c636-491d-91c4-b294c4be2800' User entered 'None (0)'	System	11 Sep 2020 23:57:09
	System	11 Sep 2020 23:57:09

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-11T18:56:52', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '1c9db203-c636-491d-91c4-b294c4be2800'	System	11 Sep 2020 23:57:09
User entered 'None (0)'	System	11 Sep 2020 23:57:09

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-11T18:56:56', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '1c9db203-c636-491d-91c4-b294c4be2800'	System	11 Sep 2020 23:57:09
User entered 'None (0)'	System	11 Sep 2020 23:57:09

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-11T18:57:01', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '1c9db203-c636-491d-91c4-b294c4be2800'	System	11 Sep 2020 23:57:09
User entered 'No (N)'	System	11 Sep 2020 23:57:09

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-11T18:57:07', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '1c9db203-c636-491d-91c4-b294c4be2800'	System	11 Sep 2020 23:57:09
User entered '11 Sep 2020 18:57'	System	11 Sep 2020 23:57:09

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 5'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T08:12:33', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '552cf2e2-6013-4582-91ce-849439969205'	System	13 Sep 2020 13:13:04
User entered 'None (0)'	System	13 Sep 2020 13:13:04

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T08:12:37', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '552cf2e2-6013-4582-91ce-849439969205'	System	13 Sep 2020 13:13:04
User entered 'None (0)'	System	13 Sep 2020 13:13:04

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T08:12:40', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '552cf2e2-6013-4582-91ce-849439969205'	System	13 Sep 2020 13:13:04
User entered 'None (0)'	System	13 Sep 2020 13:13:04

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T08:12:44', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '552cf2e2-6013-4582-91ce-849439969205'	System	13 Sep 2020 13:13:04
User entered 'None (0)'	System	13 Sep 2020 13:13:04

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T08:12:47', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '552cf2e2-6013-4582-91ce-849439969205' User entered 'None (0)'	System	13 Sep 2020 13:13:04
	System	13 Sep 2020 13:13:04

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T08:12:50', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '552cf2e2-6013-4582-91ce-849439969205'	System	13 Sep 2020 13:13:04
User entered 'None (0)'	System	13 Sep 2020 13:13:04

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T08:12:54', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '552cf2e2-6013-4582-91ce-849439969205'	System	13 Sep 2020 13:13:04
User entered 'No (N)'	System	13 Sep 2020 13:13:04

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T08:12:59', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '552cf2e2-6013-4582-91ce-849439969205'	System	13 Sep 2020 13:13:04
User entered '13 Sep 2020 08:12'	System	13 Sep 2020 13:13:04

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 6'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T21:25:34', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'c62affdc-fc9d-4a24-b81b-9c7bc12467a0'	System	14 Sep 2020 02:26:06
User entered 'None (0)'	System	14 Sep 2020 02:26:06

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T21:25:37', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'c62affdc-fc9d-4a24-b81b-9c7bc12467a0'	System	14 Sep 2020 02:26:06
User entered 'None (0)'	System	14 Sep 2020 02:26:06

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T21:25:40', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'c62affdc-fc9d-4a24-b81b-9c7bc12467a0'	System	14 Sep 2020 02:26:06
User entered 'None (0)'	System	14 Sep 2020 02:26:06

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T21:25:43', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'c62affdc-fc9d-4a24-b81b-9c7bc12467a0'	System	14 Sep 2020 02:26:06
User entered 'None (0)'	System	14 Sep 2020 02:26:06

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T21:25:47', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'c62affdc-fc9d-4a24-b81b-9c7bc12467a0'	System	14 Sep 2020 02:26:06
User entered 'None (0)'	System	14 Sep 2020 02:26:06

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T21:25:50', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'c62affdc-fc9d-4a24-b81b-9c7bc12467a0'	System	14 Sep 2020 02:26:06
User entered 'None (0)'	System	14 Sep 2020 02:26:06

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T21:25:53', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'c62affdc-fc9d-4a24-b81b-9c7bc12467a0'	System	14 Sep 2020 02:26:06
User entered 'No (N)'	System	14 Sep 2020 02:26:06

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-13T21:26:01', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'c62affdc-fc9d-4a24-b81b-9c7bc12467a0'	System	14 Sep 2020 02:26:06
User entered '13 Sep 2020 21:26'	System	14 Sep 2020 02:26:06

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 7'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-14T19:41:59', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ef1efa2d-5e95-45e9-9f90-17ad5f7acb83'	System	15 Sep 2020 00:42:32
User entered 'None (0)'	System	15 Sep 2020 00:42:32

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-14T19:42:03', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ef1efa2d-5e95-45e9-9f90-17ad5f7acb83'	System	15 Sep 2020 00:42:32
User entered 'None (0)'	System	15 Sep 2020 00:42:32

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-14T19:42:07', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ef1efa2d-5e95-45e9-9f90-17ad5f7acb83'	System	15 Sep 2020 00:42:32
User entered 'None (0)'	System	15 Sep 2020 00:42:32

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-14T19:42:11', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ef1efa2d-5e95-45e9-9f90-17ad5f7acb83'	System	15 Sep 2020 00:42:32
User entered 'None (0)'	System	15 Sep 2020 00:42:32

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-14T19:42:14', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ef1efa2d-5e95-45e9-9f90-17ad5f7acb83'	System	15 Sep 2020 00:42:32
User entered 'None (0)'	System	15 Sep 2020 00:42:32

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-14T19:42:17', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ef1efa2d-5e95-45e9-9f90-17ad5f7acb83'	System	15 Sep 2020 00:42:32
User entered 'None (0)'	System	15 Sep 2020 00:42:32

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-14T19:42:21', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ef1efa2d-5e95-45e9-9f90-17ad5f7acb83'	System	15 Sep 2020 00:42:32
User entered 'No (N)'	System	15 Sep 2020 00:42:32

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-09-14T19:42:26', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'ef1efa2d-5e95-45e9-9f90-17ad5f7acb83'	System	15 Sep 2020 00:42:32
User entered '14 Sep 2020 19:42'	System	15 Sep 2020 00:42:32

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 18:49:13

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:29
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	15 Sep 2020 18:42:09

US3782162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '15 Sep 2020'	Carlton Griffin (b) (4)	15 Sep 2020 18:42:09

US3782162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	15 Sep 2020 18:42:09

US3782162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4) Carlton Griffin (b) (4)	15 Sep 2020 18:42:09

US3782162

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	15 Sep 2020 18:42:13

US3782162

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'I'	System	15 Sep 2020 18:42:13

US3782162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	22 Sep 2020 20:51:59

US3782162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '22 Sep 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Sep 2020 20:51:59

US3782162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	22 Sep 2020 20:51:59

US3782162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Sep 2020 20:51:59

US3782162

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	22 Sep 2020 20:52:03

US3782162

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'I'	System	22 Sep 2020 20:52:03

US3782162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	29 Sep 2020 17:49:59

US3782162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '29 Sep 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	29 Sep 2020 17:49:59

US3782162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	29 Sep 2020 17:49:59

US3782162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4) Carlton Griffin (b) (4)	29 Sep 2020 17:49:59
	(b) (4)	

US3782162

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	29 Sep 2020 17:50:07

US3782162

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'I'	System	29 Sep 2020 17:50:07

US3782162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:43:02

US3782162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:43:02

US3782162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:43:02

US3782162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'VISIT2'	System	09 Oct 2020 17:43:02

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '12:08'	(b) (4), (b) (6)	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered '9 Oct 2020 12:08'	System	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '98.3' F	(b) (4), (b) (6)	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '91'	(b) (4), (b) (6)	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'bpm'	System	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '16'	(b) (4), (b) (6)	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'breaths/min'	System	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '110'	(b) (4), (b) (6)	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'mmHg'	System	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User closed query 'per CDM RQ : value is out of range, please confirm whether CS/NCS and report as AE, if appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:07:20
Query 'per CDM RQ : value is out of range, please confirm whether CS/NCS and report as AE, if appropriate' answered with 'NCS' (Site from DM).	Carlton Griffin (b) (4)	12 Oct 2020 14:28:26
User opened query 'per CDM RQ : value is out of range, please confirm whether CS/NCS and report as AE, if appropriate' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:21:22
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 11:21:02
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Bp appropriate' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 18:13:15
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		09 Oct 2020 18:12:51
User entered '59'	(b) (4), (b) (6)	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:45:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'mmHg'	System	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '13:21' reason for change: Data Entry Error	(b) (4)	
	Carlton Griffin (b) (4)	12 Oct 2020 14:36:28
User entered '12:21'	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered '9 Oct 2020 13:21'	System	12 Oct 2020 14:36:28
User entered '9 Oct 2020 12:21'	System	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '98' F	(b) (4), (b) (6)	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '97'	(b) (4), (b) (6)	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'bpm'	System	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '16'	(b) (4), (b) (6)	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'breaths/min'	System	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '112'	(b) (4), (b) (6)	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'mmHg'	System	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User closed query 'per CDM RQ : value is out of range, please confirm whether CS/NCS and report as AE, if appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:07:26
Query 'per CDM RQ : value is out of range, please confirm whether CS/NCS and report as AE, if appropriate' answered with 'NCS' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	12 Oct 2020 14:28:39
User opened query 'per CDM RQ : value is out of range, please confirm whether CS/NCS and report as AE, if appropriate' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:21:58
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 11:21:41
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'normal BP for participant' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 18:22:37
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		09 Oct 2020 18:22:16
User entered '55'	(b) (4), (b) (6)	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:45:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'mmHg'	System	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:43:09

US3782162

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:43:09

US3782162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:06:13

US3782162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:06:13

US3782162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:06:13

US3782162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'MRNA-1273 OR PLACEBO'	System	09 Oct 2020 18:06:13

US3782162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:06:13

US3782162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '12:50'	(b) (4), (b) (6)	09 Oct 2020 18:06:13

US3782162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered '9 Oct 2020 12:50'	System	09 Oct 2020 18:06:13

US3782162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:06:13

US3782162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'ONCE'	System	09 Oct 2020 18:06:13

US3782162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:45:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'INTRAMUSCULAR'	System	09 Oct 2020 18:06:13

US3782162

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:47:10

US3782162

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:47:10

US3782162

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '12:20'	(b) (4), (b) (6)	09 Oct 2020 17:47:10

US3782162

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered '9 Oct 2020 12:20'	System	09 Oct 2020 17:47:10

US3782162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:45:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:47:25

US3782162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	09 Oct 2020 17:47:25

US3782162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:47:25

US3782162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:13

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '12:25'	(b) (4), (b) (6)	09 Oct 2020 17:47:25

US3782162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:45:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered '9 Oct 2020 12:25'	System	09 Oct 2020 17:47:25

US3782162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	09 Oct 2020 17:47:25

US3782162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 17:47:25

US3782162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 17:47:25

US3782162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:45:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered empty.	System	09 Oct 2020 17:47:25

US3782162

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:47:30

US3782162

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'I'	System	09 Oct 2020 17:47:30

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T13:24:53', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f3de1d38-9644-4bc2-b89d-23ff7d2eacec'	System	09 Oct 2020 18:25:51
User entered 'Yes (Y)'	System	09 Oct 2020 18:25:51

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T13:25:26', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f3de1d38-9644-4bc2-b89d-23ff7d2eacec'	System	09 Oct 2020 18:25:51
User entered '98.0'	System	09 Oct 2020 18:25:51

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T13:25:37', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f3de1d38-9644-4bc2-b89d-23ff7d2eacec'	System	09 Oct 2020 18:25:51
User entered 'No (N)'	System	09 Oct 2020 18:25:51

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T13:25:46', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f3de1d38-9644-4bc2-b89d-23ff7d2eacec'	System	09 Oct 2020 18:25:51
User entered '09 Oct 2020 13:25'	System	09 Oct 2020 18:25:51

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '09 Oct 2020 13:10'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '09 Oct 2020 15:40'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T19:10:33', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'b6133a36-cee4-4a56-8830-f4cb07051467'	System	10 Oct 2020 00:11:08
User entered 'Yes (Y)'	System	10 Oct 2020 00:11:08

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T19:10:42', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'b6133a36-cee4-4a56-8830-f4cb07051467' User entered '97.7'	System	10 Oct 2020 00:11:08
	System	10 Oct 2020 00:11:08

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T19:10:50', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'b6133a36-cee4-4a56-8830-f4cb07051467'	System	10 Oct 2020 00:11:08
User entered 'Yes (Y)'	System	10 Oct 2020 00:11:08

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T19:10:58', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'b6133a36-cee4-4a56-8830-f4cb07051467' User entered '0'	System	10 Oct 2020 00:11:08
	System	10 Oct 2020 00:11:08

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'med entered on con med form' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 07:31:11
Query 'Per the participant response, medication was taken to prevent 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 'med entered on con med form' (Site from System).	(b) (4), (b) (6)	10 Oct 2020 20:48:18
User opened query 'Per the participant response, medication was taken to prevent 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).	System	10 Oct 2020 00:11:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T19:10:58', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'b6133a36-cee4-4a56-8830-f4cb07051467'	System	10 Oct 2020 00:11:08
User entered '1'	System	10 Oct 2020 00:11:08

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T19:11:04', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'b6133a36-cee4-4a56-8830-f4cb07051467'	System	10 Oct 2020 00:11:08
User entered '09 Oct 2020 19:11'	System	10 Oct 2020 00:11:08

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '09 Oct 2020 16:35'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 2'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-10T20:25:33', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '4db7729c-5027-4b64-a142-6ee997e22fe2'	System	11 Oct 2020 01:25:58
User entered 'Yes (Y)'	System	11 Oct 2020 01:25:58

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-10T20:25:44', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '4db7729c-5027-4b64-a142-6ee997e22fe2'	System	11 Oct 2020 01:25:58
User entered '98.0'	System	11 Oct 2020 01:25:58

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-10T20:25:48', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '4db7729c-5027-4b64-a142-6ee997e22fe2'	System	11 Oct 2020 01:25:58
User entered 'No (N)'	System	11 Oct 2020 01:25:58

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-10T20:25:55', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '4db7729c-5027-4b64-a142-6ee997e22fe2'	System	11 Oct 2020 01:25:58
User entered '10 Oct 2020 20:25'	System	11 Oct 2020 01:25:58

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 3'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-11T20:52:57', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '34453459-ad4c-4730-8ec4-de9e91fcf504'	System	12 Oct 2020 01:53:21
User entered 'Yes (Y)'	System	12 Oct 2020 01:53:21

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-11T20:53:07', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '34453459-ad4c-4730-8ec4-de9e91fcf504'	System	12 Oct 2020 01:53:21
User entered '97.8'	System	12 Oct 2020 01:53:21

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-11T20:53:12', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '34453459-ad4c-4730-8ec4-de9e91fcf504'	System	12 Oct 2020 01:53:21
User entered 'No (N)'	System	12 Oct 2020 01:53:21

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-11T20:53:18', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '34453459-ad4c-4730-8ec4-de9e91fcf504'	System	12 Oct 2020 01:53:21
User entered '11 Oct 2020 20:53'	System	12 Oct 2020 01:53:21

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 4'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-12T20:10:19', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '312a49ec-a9b8-4d0f-906f-382200281799'	System	13 Oct 2020 01:10:40
User entered 'Yes (Y)'	System	13 Oct 2020 01:10:40

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-12T20:10:26', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '312a49ec-a9b8-4d0f-906f-382200281799'	System	13 Oct 2020 01:10:40
User entered '98.5'	System	13 Oct 2020 01:10:40

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-12T20:10:31', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '312a49ec-a9b8-4d0f-906f-382200281799'	System	13 Oct 2020 01:10:40
User entered 'No (N)'	System	13 Oct 2020 01:10:40

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-12T20:10:36', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '312a49ec-a9b8-4d0f-906f-382200281799'	System	13 Oct 2020 01:10:40
User entered '12 Oct 2020 20:10'	System	13 Oct 2020 01:10:40

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 5'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-13T19:41:08', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '196cba05-b554-4d77-a334-f51686c3d8f1'	System	14 Oct 2020 00:41:39
User entered 'Yes (Y)'	System	14 Oct 2020 00:41:39

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-13T19:41:18', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '196cba05-b554-4d77-a334-f51686c3d8f1'	System	14 Oct 2020 00:41:39
User entered '97.0'	System	14 Oct 2020 00:41:39

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-13T19:41:23', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '196cba05-b554-4d77-a334-f51686c3d8f1'	System	14 Oct 2020 00:41:39
User entered 'No (N)'	System	14 Oct 2020 00:41:39

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-13T19:41:32', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '196cba05-b554-4d77-a334-f51686c3d8f1'	System	14 Oct 2020 00:41:39
User entered '13 Oct 2020 19:41'	System	14 Oct 2020 00:41:39

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 6'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-14T20:27:24', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0570d89b-2654-402d-b8b9-652beb30c82a'	System	15 Oct 2020 01:27:56
User entered 'Yes (Y)'	System	15 Oct 2020 01:27:56

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-14T20:27:33', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0570d89b-2654-402d-b8b9-652beb30c82a' User entered '97.5'	System	15 Oct 2020 01:27:56
	System	15 Oct 2020 01:27:56

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-14T20:27:40', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0570d89b-2654-402d-b8b9-652beb30c82a'	System	15 Oct 2020 01:27:56
User entered 'Yes (Y)'	System	15 Oct 2020 01:27:56

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:13

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
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 'participant contacted. con med pages updated ' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 22:36:06
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).	Carlton Griffin (b) (4)	19 Oct 2020 12:42:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-14T20:27:48', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0570d89b-2654-402d-b8b9-652beb30c82a'	(b) (4)	
User entered '1'	System	15 Oct 2020 01:27:56
	System	15 Oct 2020 01:27:56
	System	15 Oct 2020 01:27:56

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:13

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-14T20:27:48', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0570d89b-2654-402d-b8b9-652beb30c82a' User entered '0'	System	15 Oct 2020 01:27:56
	System	15 Oct 2020 01:27:56

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-14T20:27:53', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0570d89b-2654-402d-b8b9-652beb30c82a'	System	15 Oct 2020 01:27:56
User entered '14 Oct 2020 20:27'	System	15 Oct 2020 01:27:56

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 7'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-15T20:13:19', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '294a8ca8-ccf1-48eb-a365-63d26dc7078f'	System	16 Oct 2020 01:13:54
User entered 'Yes (Y)'	System	16 Oct 2020 01:13:54

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-15T20:13:26', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '294a8ca8-ccf1-48eb-a365-63d26dc7078f'	System	16 Oct 2020 01:13:54
User entered '97.8'	System	16 Oct 2020 01:13:54

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-15T20:13:37', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '294a8ca8-ccf1-48eb-a365-63d26dc7078f'	System	16 Oct 2020 01:13:54
User entered 'Yes (Y)'	System	16 Oct 2020 01:13:54

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:13

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
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 'participant contacted. con med page updated' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 22:36:10
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 (989ecb69765dc1e1)', Time: '2020-10-15T20:13:44', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '294a8ca8-ccf1-48eb-a365-63d26dc7078f' User entered '1'	Carlton Griffin (b) (4)	19 Oct 2020 12:42:45
	System	16 Oct 2020 01:13:54
	System	16 Oct 2020 01:13:54
	System	16 Oct 2020 01:13:54

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:13

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-15T20:13:44', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '294a8ca8-ccf1-48eb-a365-63d26dc7078f' User entered '0'	System	16 Oct 2020 01:13:54
	System	16 Oct 2020 01:13:54

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-15T20:13:49', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '294a8ca8-ccf1-48eb-a365-63d26dc7078f' User entered '15 Oct 2020 20:13'	System	16 Oct 2020 01:13:54
	System	16 Oct 2020 01:13:54

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	15 Oct 2020 01:27:56
User entered 'Day 8'	System	15 Oct 2020 01:27:56

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:45:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-17T10:08:02', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '5badf136-e806-480b-9328-405eb9ecad03'	System	17 Oct 2020 15:08:35
User entered 'Yes (Y)'	System	17 Oct 2020 15:08:35

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:45:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-17T10:08:17', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '5badf136-e806-480b-9328-405eb9ecad03'	System	17 Oct 2020 15:08:35
User entered '97.5'	System	17 Oct 2020 15:08:35

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:45:13

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-17T10:08:23', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '5badf136-e806-480b-9328-405eb9ecad03'	System	17 Oct 2020 15:08:35
User entered 'No (N)'	System	17 Oct 2020 15:08:35

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-17T10:08:29', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '5badf136-e806-480b-9328-405eb9ecad03'	System	17 Oct 2020 15:08:35
User entered '17 Oct 2020 10:08'	System	17 Oct 2020 15:08:35

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 01:27:56

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 01:27:56

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T13:26:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '3b16a378-06de-4746-ade2-37af2af74d5a'	System	09 Oct 2020 18:26:22
User entered 'None (1)'	System	09 Oct 2020 18:26:22

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T13:26:04', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '3b16a378-06de-4746-ade2-37af2af74d5a'	System	09 Oct 2020 18:26:22
User entered 'No (N)'	System	09 Oct 2020 18:26:22

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T13:26:08', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '3b16a378-06de-4746-ade2-37af2af74d5a'	System	09 Oct 2020 18:26:22
User entered 'No (N)'	System	09 Oct 2020 18:26:22

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T13:26:13', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '3b16a378-06de-4746-ade2-37af2af74d5a'	System	09 Oct 2020 18:26:22
User entered 'None (1)'	System	09 Oct 2020 18:26:22

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T13:26:18', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '3b16a378-06de-4746-ade2-37af2af74d5a'	System	09 Oct 2020 18:26:22
User entered '09 Oct 2020 13:26'	System	09 Oct 2020 18:26:22

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '09 Oct 2020 13:10'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '09 Oct 2020 15:40'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T19:11:15', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '30f17575-b4bd-4589-b4d1-dc538cdc37a8'	System	10 Oct 2020 00:11:37
User entered 'None (1)'	System	10 Oct 2020 00:11:37

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T19:11:20', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '30f17575-b4bd-4589-b4d1-dc538cdc37a8'	System	10 Oct 2020 00:11:37
User entered 'No (N)'	System	10 Oct 2020 00:11:37

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T19:11:23', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '30f17575-b4bd-4589-b4d1-dc538cdc37a8'	System	10 Oct 2020 00:11:37
User entered 'No (N)'	System	10 Oct 2020 00:11:37

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T19:11:27', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '30f17575-b4bd-4589-b4d1-dc538cdc37a8'	System	10 Oct 2020 00:11:37
User entered 'None (1)'	System	10 Oct 2020 00:11:37

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T19:11:32', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '30f17575-b4bd-4589-b4d1-dc538cdc37a8'	System	10 Oct 2020 00:11:37
User entered '09 Oct 2020 19:11'	System	10 Oct 2020 00:11:37

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '09 Oct 2020 16:35'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 2'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-10T20:26:52', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '722b76a1-3bdb-4ea9-b3d9-92fa66d702f1'	System	11 Oct 2020 01:26:59
User entered 'Does not interfere with activity (2)'	System	11 Oct 2020 01:26:59

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-10T20:26:06', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '722b76a1-3bdb-4ea9-b3d9-92fa66d702f1'	System	11 Oct 2020 01:26:59
User entered 'No (N)'	System	11 Oct 2020 01:26:59

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-10T20:26:13', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '722b76a1-3bdb-4ea9-b3d9-92fa66d702f1'	System	11 Oct 2020 01:26:59
User entered 'No (N)'	System	11 Oct 2020 01:26:59

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-10T20:26:20', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '722b76a1-3bdb-4ea9-b3d9-92fa66d702f1'	System	11 Oct 2020 01:26:59
User entered 'None (1)'	System	11 Oct 2020 01:26:59

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-10T20:26:57', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '722b76a1-3bdb-4ea9-b3d9-92fa66d702f1'	System	11 Oct 2020 01:26:59
User entered '10 Oct 2020 20:26'	System	11 Oct 2020 01:26:59

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 3'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-11T20:53:36', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '2ba3ec33-d785-4a92-a052-367620929bb1'	System	12 Oct 2020 01:54:10
User entered 'None (1)'	System	12 Oct 2020 01:54:10

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-11T20:53:44', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '2ba3ec33-d785-4a92-a052-367620929bb1'	System	12 Oct 2020 01:54:10
User entered 'No (N)'	System	12 Oct 2020 01:54:10

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-11T20:53:48', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '2ba3ec33-d785-4a92-a052-367620929bb1'	System	12 Oct 2020 01:54:10
User entered 'No (N)'	System	12 Oct 2020 01:54:10

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-11T20:53:54', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '2ba3ec33-d785-4a92-a052-367620929bb1'	System	12 Oct 2020 01:54:10
User entered 'None (1)'	System	12 Oct 2020 01:54:10

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-11T20:54:02', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '2ba3ec33-d785-4a92-a052-367620929bb1'	System	12 Oct 2020 01:54:10
User entered '11 Oct 2020 20:54'	System	12 Oct 2020 01:54:10

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 4'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-12T20:10:42', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '5dc2005a-6b57-49dd-8dcf-80472e53f574'	System	13 Oct 2020 01:11:02
User entered 'None (1)'	System	13 Oct 2020 01:11:02

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-12T20:10:47', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '5dc2005a-6b57-49dd-8dcf-80472e53f574'	System	13 Oct 2020 01:11:02
User entered 'No (N)'	System	13 Oct 2020 01:11:02

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-12T20:10:50', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '5dc2005a-6b57-49dd-8dcf-80472e53f574'	System	13 Oct 2020 01:11:02
User entered 'No (N)'	System	13 Oct 2020 01:11:02

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-12T20:10:54', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '5dc2005a-6b57-49dd-8dcf-80472e53f574'	System	13 Oct 2020 01:11:02
User entered 'None (1)'	System	13 Oct 2020 01:11:02

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-12T20:10:57', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '5dc2005a-6b57-49dd-8dcf-80472e53f574'	System	13 Oct 2020 01:11:02
User entered '12 Oct 2020 20:10'	System	13 Oct 2020 01:11:02

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 5'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-13T19:41:40', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '42b8e468-c7d1-43f3-9f68-0002ae4e9bc8'	System	14 Oct 2020 00:42:00
User entered 'None (1)'	System	14 Oct 2020 00:42:00

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-13T19:41:44', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '42b8e468-c7d1-43f3-9f68-0002ae4e9bc8'	System	14 Oct 2020 00:42:00
User entered 'No (N)'	System	14 Oct 2020 00:42:00

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-13T19:41:47', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '42b8e468-c7d1-43f3-9f68-0002ae4e9bc8'	System	14 Oct 2020 00:42:00
User entered 'No (N)'	System	14 Oct 2020 00:42:00

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-13T19:41:51', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '42b8e468-c7d1-43f3-9f68-0002ae4e9bc8'	System	14 Oct 2020 00:42:00
User entered 'None (1)'	System	14 Oct 2020 00:42:00

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-13T19:41:56', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '42b8e468-c7d1-43f3-9f68-0002ae4e9bc8'	System	14 Oct 2020 00:42:00
User entered '13 Oct 2020 19:41'	System	14 Oct 2020 00:42:00

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 6'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-14T20:28:03', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '6212875c-ba9f-47ed-9f52-adf13a03a0bb'	System	15 Oct 2020 01:28:26
User entered 'None (1)'	System	15 Oct 2020 01:28:26

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-14T20:28:08', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '6212875c-ba9f-47ed-9f52-adf13a03a0bb'	System	15 Oct 2020 01:28:26
User entered 'No (N)'	System	15 Oct 2020 01:28:26

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-14T20:28:13', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '6212875c-ba9f-47ed-9f52-adf13a03a0bb'	System	15 Oct 2020 01:28:26
User entered 'No (N)'	System	15 Oct 2020 01:28:26

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-14T20:28:18', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '6212875c-ba9f-47ed-9f52-adf13a03a0bb'	System	15 Oct 2020 01:28:26
User entered 'None (1)'	System	15 Oct 2020 01:28:26

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-14T20:28:23', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '6212875c-ba9f-47ed-9f52-adf13a03a0bb'	System	15 Oct 2020 01:28:26
User entered '14 Oct 2020 20:28'	System	15 Oct 2020 01:28:26

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 7'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:13

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-15T20:13:55', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '3a99ded7-5365-4ba6-ab20-de246c270768'	System	16 Oct 2020 01:14:17
User entered 'None (1)'	System	16 Oct 2020 01:14:17

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-15T20:13:58', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '3a99ded7-5365-4ba6-ab20-de246c270768'	System	16 Oct 2020 01:14:17
User entered 'No (N)'	System	16 Oct 2020 01:14:17

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:13

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-15T20:14:02', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '3a99ded7-5365-4ba6-ab20-de246c270768'	System	16 Oct 2020 01:14:17
User entered 'No (N)'	System	16 Oct 2020 01:14:17

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:13

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-15T20:14:05', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '3a99ded7-5365-4ba6-ab20-de246c270768'	System	16 Oct 2020 01:14:17
User entered 'None (1)'	System	16 Oct 2020 01:14:17

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-15T20:14:11', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '3a99ded7-5365-4ba6-ab20-de246c270768'	System	16 Oct 2020 01:14:17
User entered '15 Oct 2020 20:14'	System	16 Oct 2020 01:14:17

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T13:26:28', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '08d452c4-f38b-4127-8e72-7d7e7604821c'	System	09 Oct 2020 18:27:24
User entered 'None (0)'	System	09 Oct 2020 18:27:24

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T13:26:32', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '08d452c4-f38b-4127-8e72-7d7e7604821c'	System	09 Oct 2020 18:27:24
User entered 'None (0)'	System	09 Oct 2020 18:27:24

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T13:26:35', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '08d452c4-f38b-4127-8e72-7d7e7604821c' User entered 'None (0)'	System	09 Oct 2020 18:27:24
	System	09 Oct 2020 18:27:24

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T13:26:38', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '08d452c4-f38b-4127-8e72-7d7e7604821c' User entered 'None (0)'	System	09 Oct 2020 18:27:24
	System	09 Oct 2020 18:27:24

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T13:26:41', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '08d452c4-f38b-4127-8e72-7d7e7604821c'	System	09 Oct 2020 18:27:24
User entered 'None (0)'	System	09 Oct 2020 18:27:24

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T13:26:44', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '08d452c4-f38b-4127-8e72-7d7e7604821c'	System	09 Oct 2020 18:27:24
User entered 'None (0)'	System	09 Oct 2020 18:27:24

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T13:26:53', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '08d452c4-f38b-4127-8e72-7d7e7604821c'	System	09 Oct 2020 18:27:24
User entered 'No (N)'	System	09 Oct 2020 18:27:24

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T13:26:57', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '08d452c4-f38b-4127-8e72-7d7e7604821c'	System	09 Oct 2020 18:27:24
User entered '09 Oct 2020 13:26'	System	09 Oct 2020 18:27:24

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '09 Oct 2020 13:10'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '09 Oct 2020 15:40'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T19:11:39', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'e3ce31b0-e669-461c-9d80-0bc62488a700'	System	10 Oct 2020 00:12:20
User entered 'None (0)'	System	10 Oct 2020 00:12:20

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T19:11:45', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'e3ce31b0-e669-461c-9d80-0bc62488a700'	System	10 Oct 2020 00:12:20
User entered 'No interference with activity (1)'	System	10 Oct 2020 00:12:20

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T19:11:49', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'e3ce31b0-e669-461c-9d80-0bc62488a700'	System	10 Oct 2020 00:12:20
User entered 'None (0)'	System	10 Oct 2020 00:12:20

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T19:11:52', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'e3ce31b0-e669-461c-9d80-0bc62488a700'	System	10 Oct 2020 00:12:20
User entered 'None (0)'	System	10 Oct 2020 00:12:20

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T19:11:56', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'e3ce31b0-e669-461c-9d80-0bc62488a700'	System	10 Oct 2020 00:12:20
User entered 'None (0)'	System	10 Oct 2020 00:12:20

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T19:11:59', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'e3ce31b0-e669-461c-9d80-0bc62488a700'	System	10 Oct 2020 00:12:20
User entered 'None (0)'	System	10 Oct 2020 00:12:20

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T19:12:03', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'e3ce31b0-e669-461c-9d80-0bc62488a700'	System	10 Oct 2020 00:12:20
User entered 'No (N)'	System	10 Oct 2020 00:12:20

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-09T19:12:13', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'e3ce31b0-e669-461c-9d80-0bc62488a700'	System	10 Oct 2020 00:12:20
User entered '09 Oct 2020 19:12'	System	10 Oct 2020 00:12:20

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '09 Oct 2020 16:35'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 2'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-10T20:27:06', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'df2b5db6-c351-47e3-be2e-c539c628fd56'	System	11 Oct 2020 01:27:45
User entered 'None (0)'	System	11 Oct 2020 01:27:45

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-10T20:27:10', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'df2b5db6-c351-47e3-be2e-c539c628fd56'	System	11 Oct 2020 01:27:45
User entered 'No interference with activity (1)'	System	11 Oct 2020 01:27:45

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-10T20:27:19', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'df2b5db6-c351-47e3-be2e-c539c628fd56'	System	11 Oct 2020 01:27:45
User entered 'None (0)'	System	11 Oct 2020 01:27:45

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-10T20:27:24', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'df2b5db6-c351-47e3-be2e-c539c628fd56'	System	11 Oct 2020 01:27:45
User entered 'None (0)'	System	11 Oct 2020 01:27:45

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-10T20:27:27', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'df2b5db6-c351-47e3-be2e-c539c628fd56'	System	11 Oct 2020 01:27:45
User entered 'None (0)'	System	11 Oct 2020 01:27:45

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-10T20:27:30', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'df2b5db6-c351-47e3-be2e-c539c628fd56'	System	11 Oct 2020 01:27:45
User entered 'None (0)'	System	11 Oct 2020 01:27:45

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-10T20:27:35', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'df2b5db6-c351-47e3-be2e-c539c628fd56'	System	11 Oct 2020 01:27:45
User entered 'No (N)'	System	11 Oct 2020 01:27:45

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-10T20:27:42', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'df2b5db6-c351-47e3-be2e-c539c628fd56'	System	11 Oct 2020 01:27:45
User entered '10 Oct 2020 20:27'	System	11 Oct 2020 01:27:45

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 3'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-11T20:54:16', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '605a3157-5e9d-4d51-85cb-d648a79db457'	System	12 Oct 2020 01:54:46
User entered 'None (0)'	System	12 Oct 2020 01:54:46

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-11T20:54:20', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '605a3157-5e9d-4d51-85cb-d648a79db457'	System	12 Oct 2020 01:54:46
User entered 'None (0)'	System	12 Oct 2020 01:54:46

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-11T20:54:23', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '605a3157-5e9d-4d51-85cb-d648a79db457'	System	12 Oct 2020 01:54:46
User entered 'None (0)'	System	12 Oct 2020 01:54:46

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-11T20:54:27', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '605a3157-5e9d-4d51-85cb-d648a79db457'	System	12 Oct 2020 01:54:46
User entered 'None (0)'	System	12 Oct 2020 01:54:46

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-11T20:54:30', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '605a3157-5e9d-4d51-85cb-d648a79db457'	System	12 Oct 2020 01:54:46
User entered 'None (0)'	System	12 Oct 2020 01:54:46

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-11T20:54:34', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '605a3157-5e9d-4d51-85cb-d648a79db457'	System	12 Oct 2020 01:54:46
User entered 'None (0)'	System	12 Oct 2020 01:54:46

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-11T20:54:37', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '605a3157-5e9d-4d51-85cb-d648a79db457'	System	12 Oct 2020 01:54:46
User entered 'No (N)'	System	12 Oct 2020 01:54:46

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-11T20:54:42', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '605a3157-5e9d-4d51-85cb-d648a79db457'	System	12 Oct 2020 01:54:46
User entered '11 Oct 2020 20:54'	System	12 Oct 2020 01:54:46

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 4'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-12T20:11:04', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'b7d7b215-e3a4-4a93-b9b3-698c34cd5aae'	System	13 Oct 2020 01:11:35
User entered 'None (0)'	System	13 Oct 2020 01:11:35

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-12T20:11:09', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'b7d7b215-e3a4-4a93-b9b3-698c34cd5aae'	System	13 Oct 2020 01:11:35
User entered 'No interference with activity (1)'	System	13 Oct 2020 01:11:35

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-12T20:11:12', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'b7d7b215-e3a4-4a93-b9b3-698c34cd5aae'	System	13 Oct 2020 01:11:35
User entered 'None (0)'	System	13 Oct 2020 01:11:35

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-12T20:11:15', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'b7d7b215-e3a4-4a93-b9b3-698c34cd5aae'	System	13 Oct 2020 01:11:35
User entered 'None (0)'	System	13 Oct 2020 01:11:35

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-12T20:11:19', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'b7d7b215-e3a4-4a93-b9b3-698c34cd5aae'	System	13 Oct 2020 01:11:35
User entered 'None (0)'	System	13 Oct 2020 01:11:35

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-12T20:11:22', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'b7d7b215-e3a4-4a93-b9b3-698c34cd5aae'	System	13 Oct 2020 01:11:35
User entered 'None (0)'	System	13 Oct 2020 01:11:35

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-12T20:11:26', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'b7d7b215-e3a4-4a93-b9b3-698c34cd5aae'	System	13 Oct 2020 01:11:35
User entered 'No (N)'	System	13 Oct 2020 01:11:35

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-12T20:11:29', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'b7d7b215-e3a4-4a93-b9b3-698c34cd5aae'	System	13 Oct 2020 01:11:35
User entered '12 Oct 2020 20:11'	System	13 Oct 2020 01:11:35

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 5'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-13T19:42:03', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f9d331ea-959d-4618-8723-5410ec4914c2'	System	14 Oct 2020 00:42:36
User entered 'None (0)'	System	14 Oct 2020 00:42:36

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-13T19:42:06', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f9d331ea-959d-4618-8723-5410ec4914c2'	System	14 Oct 2020 00:42:36
User entered 'None (0)'	System	14 Oct 2020 00:42:36

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-13T19:42:09', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f9d331ea-959d-4618-8723-5410ec4914c2'	System	14 Oct 2020 00:42:36
User entered 'None (0)'	System	14 Oct 2020 00:42:36

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-13T19:42:12', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f9d331ea-959d-4618-8723-5410ec4914c2'	System	14 Oct 2020 00:42:36
User entered 'None (0)'	System	14 Oct 2020 00:42:36

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-13T19:42:15', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f9d331ea-959d-4618-8723-5410ec4914c2'	System	14 Oct 2020 00:42:36
User entered 'None (0)'	System	14 Oct 2020 00:42:36

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-13T19:42:18', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f9d331ea-959d-4618-8723-5410ec4914c2'	System	14 Oct 2020 00:42:36
User entered 'None (0)'	System	14 Oct 2020 00:42:36

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-13T19:42:23', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f9d331ea-959d-4618-8723-5410ec4914c2'	System	14 Oct 2020 00:42:36
User entered 'No (N)'	System	14 Oct 2020 00:42:36

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-13T19:42:26', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f9d331ea-959d-4618-8723-5410ec4914c2'	System	14 Oct 2020 00:42:36
User entered '13 Oct 2020 19:42'	System	14 Oct 2020 00:42:36

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 6'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-14T20:28:37', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '90556b23-3dc3-4853-a52d-d91857da0661'	System	15 Oct 2020 01:29:33
User entered 'None (0)'	System	15 Oct 2020 01:29:33

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-14T20:28:44', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '90556b23-3dc3-4853-a52d-d91857da0661' User entered 'None (0)'	System	15 Oct 2020 01:29:33
	System	15 Oct 2020 01:29:33

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-14T20:28:52', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '90556b23-3dc3-4853-a52d-d91857da0661'	System	15 Oct 2020 01:29:33
User entered 'None (0)'	System	15 Oct 2020 01:29:33

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-14T20:28:57', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '90556b23-3dc3-4853-a52d-d91857da0661'	System	15 Oct 2020 01:29:33
User entered 'None (0)'	System	15 Oct 2020 01:29:33

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-14T20:29:01', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '90556b23-3dc3-4853-a52d-d91857da0661'	System	15 Oct 2020 01:29:33
User entered 'None (0)'	System	15 Oct 2020 01:29:33

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-14T20:29:04', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '90556b23-3dc3-4853-a52d-d91857da0661'	System	15 Oct 2020 01:29:33
User entered 'None (0)'	System	15 Oct 2020 01:29:33

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-14T20:29:10', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '90556b23-3dc3-4853-a52d-d91857da0661'	System	15 Oct 2020 01:29:33
User entered 'Yes (Y)'	System	15 Oct 2020 01:29:33

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-14T20:29:31', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '90556b23-3dc3-4853-a52d-d91857da0661'	System	15 Oct 2020 01:29:33
User entered '14 Oct 2020 20:29'	System	15 Oct 2020 01:29:33

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	09 Oct 2020 18:06:13
User entered 'Day 7'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-15T20:14:16', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '9c36af88-9e23-4b22-8e2e-eddad240e50c'	System	16 Oct 2020 01:14:45
User entered 'None (0)'	System	16 Oct 2020 01:14:45

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-15T20:14:19', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '9c36af88-9e23-4b22-8e2e-eddad240e50c'	System	16 Oct 2020 01:14:45
User entered 'None (0)'	System	16 Oct 2020 01:14:45

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-15T20:14:22', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '9c36af88-9e23-4b22-8e2e-eddad240e50c'	System	16 Oct 2020 01:14:45
User entered 'None (0)'	System	16 Oct 2020 01:14:45

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-15T20:14:26', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '9c36af88-9e23-4b22-8e2e-eddad240e50c'	System	16 Oct 2020 01:14:45
User entered 'None (0)'	System	16 Oct 2020 01:14:45

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-15T20:14:29', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '9c36af88-9e23-4b22-8e2e-eddad240e50c'	System	16 Oct 2020 01:14:45
User entered 'None (0)'	System	16 Oct 2020 01:14:45

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-15T20:14:32', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '9c36af88-9e23-4b22-8e2e-eddad240e50c'	System	16 Oct 2020 01:14:45
User entered 'None (0)'	System	16 Oct 2020 01:14:45

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-15T20:14:36', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '9c36af88-9e23-4b22-8e2e-eddad240e50c'	System	16 Oct 2020 01:14:45
User entered 'Yes (Y)'	System	16 Oct 2020 01:14:45

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-15T20:14:40', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '9c36af88-9e23-4b22-8e2e-eddad240e50c'	System	16 Oct 2020 01:14:45
User entered '15 Oct 2020 20:14'	System	16 Oct 2020 01:14:45

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 18:06:13

US3782162

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	15 Oct 2020 01:27:56
User entered 'Day 8'	System	15 Oct 2020 01:27:56

US3782162

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:45:13

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-17T10:08:39', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'cda6a8b3-cc6b-464a-8df9-f6383d536335'	System	17 Oct 2020 15:08:51
User entered 'No (N)'	System	17 Oct 2020 15:08:51

US3782162

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:45:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-10-17T10:08:47', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'cda6a8b3-cc6b-464a-8df9-f6383d536335'	System	17 Oct 2020 15:08:51
User entered '17 Oct 2020 10:08'	System	17 Oct 2020 15:08:51

US3782162

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:45:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 01:27:56

US3782162

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:45:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 01:27:56

US3782162

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	19 Oct 2020 03:13:50

US3782162

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '17 Oct 2020'	Carlton Griffin (b) (4)	19 Oct 2020 03:13:50

US3782162

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	19 Oct 2020 03:13:50

US3782162

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Carlton Griffin (b) (4)	19 Oct 2020 03:13:50

US3782162

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 03:13:55

US3782162

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'I'	System	19 Oct 2020 03:13:55

US3782162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:29:41

US3782162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '23 Oct 2020'	Carlton Griffin (b) (4)	23 Oct 2020 19:29:41

US3782162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:29:41

US3782162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4) Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:29:41

US3782162

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	23 Oct 2020 19:29:49

US3782162

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'I'	System	23 Oct 2020 19:29:49

US3782162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:27:13

US3782162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:27:13

US3782162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:27:13

US3782162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:27:13

US3782162

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:27:20

US3782162

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'I'	System	30 Oct 2020 20:27:20

US3782162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:13

US3782162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '6 Nov 2020'	(b) (4) Carlton Griffin (b) (4)	06 Nov 2020 16:02:13

US3782162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Clinic (Clinic)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:13

US3782162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User entered 'VISIT3'	System	06 Nov 2020 16:02:13

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '6 Nov 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '09:32'	(b) (4) Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User entered '6 Nov 2020 09:32'	System	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '98.0' F	Carlton Griffin (b) (4)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Oral (Oral)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4) Carlton Griffin (b) (4)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '74'	Carlton Griffin (b) (4)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User entered 'bpm'	System	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '20'	Carlton Griffin (b) (4)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User entered 'breaths/min'	System	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '99'	Carlton Griffin (b) (4)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User entered 'mmHg'	System	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:09:36
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:49
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		06 Nov 2020 16:02:44
User entered '53'	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User entered 'mmHg'	System	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11

US3782162

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:57

US3782162

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '6 Nov 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:57

US3782162

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	06 Nov 2020 16:03:11

US3782162

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '6 Nov 2020'	(b) (4) Carlton Griffin (b) (4)	06 Nov 2020 16:03:11

US3782162

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '09:50'	(b) (4) Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:03:11

US3782162

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:25:11
User entered '6 Nov 2020 09:50'	System	06 Nov 2020 16:03:11

US3782162

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:03:17

US3782162

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'I'	System	06 Nov 2020 16:03:17

US3782162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 64'	System	08 Sep 2020 18:49:13

US3782162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-11-09T10:14:13', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '119e86ae-da54-4d66-ace0-eeee60a39303'	System	09 Nov 2020 16:14:28
User entered 'No (N)'	System	09 Nov 2020 16:14:28

US3782162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-11-09T10:14:17', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '119e86ae-da54-4d66-ace0-eeee60a39303'	System	09 Nov 2020 16:14:28
User entered 'No (N)'	System	09 Nov 2020 16:14:28

US3782162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-11-09T10:14:24', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '119e86ae-da54-4d66-ace0-eeee60a39303'	System	09 Nov 2020 16:14:28
User entered '09 Nov 2020 10:14:24'	System	09 Nov 2020 16:14:28

US3782162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	08 Sep 2020 18:49:13
User entered '08 Nov 2020 00:01'	System	08 Sep 2020 18:49:13

US3782162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	08 Sep 2020 18:49:13
User entered '12 Nov 2020 23:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	08 Sep 2020 18:49:13
User entered 'Day 71'	System	08 Sep 2020 18:49:13

US3782162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-11-15T17:46:40', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f3173c82-3882-40ff-a277-183bbffda2bb'	System	15 Nov 2020 23:47:03
User entered 'No (N)'	System	15 Nov 2020 23:47:03

US3782162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-11-15T17:46:45', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f3173c82-3882-40ff-a277-183bbffda2bb'	System	15 Nov 2020 23:47:03
User entered 'No (N)'	System	15 Nov 2020 23:47:03

US3782162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-11-15T17:46:58', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f3173c82-3882-40ff-a277-183bbffda2bb' User entered '15 Nov 2020 17:46:58'	System	15 Nov 2020 23:47:03
	System	15 Nov 2020 23:47:03

US3782162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	08 Sep 2020 18:49:13
User entered '15 Nov 2020 00:01'	System	08 Sep 2020 18:49:13

US3782162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:03:30
Data entry locked.	System	08 Sep 2020 18:49:13
User entered '19 Nov 2020 23:59'	System	08 Sep 2020 18:49:13

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-11-20T11:25:10', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '676252de-0c28-4552-9808-df02f927ac94'	System	20 Nov 2020 17:25:31
User entered 'No (N)'	System	20 Nov 2020 17:25:31

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-11-20T11:25:17', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '676252de-0c28-4552-9808-df02f927ac94'	System	20 Nov 2020 17:25:31
User entered 'No (N)'	System	20 Nov 2020 17:25:31

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-11-20T11:25:28', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '676252de-0c28-4552-9808-df02f927ac94'	System	20 Nov 2020 17:25:31
User entered '20 Nov 2020 11:25:28'	System	20 Nov 2020 17:25:31

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-11-28T13:38:19', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '5b04171f-d573-4524-a4c4-88cf15f253ac'	System	28 Nov 2020 19:38:40
User entered 'No (N)'	System	28 Nov 2020 19:38:40

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-11-28T13:38:23', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '5b04171f-d573-4524-a4c4-88cf15f253ac'	System	28 Nov 2020 19:38:40
User entered 'No (N)'	System	28 Nov 2020 19:38:40

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-11-28T13:38:38', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '5b04171f-d573-4524-a4c4-88cf15f253ac'	System	28 Nov 2020 19:38:40
User entered '28 Nov 2020 13:38:38'	System	28 Nov 2020 19:38:40

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-12-10T12:12:31', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'd0316621-1ac4-4782-800d-bbc782a80814'	System	10 Dec 2020 18:12:45
User entered 'No (N)'	System	10 Dec 2020 18:12:45

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-12-10T12:12:35', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'd0316621-1ac4-4782-800d-bbc782a80814'	System	10 Dec 2020 18:12:45
User entered 'No (N)'	System	10 Dec 2020 18:12:45

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-12-10T12:12:42', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'd0316621-1ac4-4782-800d-bbc782a80814'	System	10 Dec 2020 18:12:45
User entered '10 Dec 2020 12:12:42'	System	10 Dec 2020 18:12:45

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-12-18T14:36:10', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '1bcce469-700f-44f2-8a72-83911624d11e'	System	18 Dec 2020 20:36:26
User entered 'No (N)'	System	18 Dec 2020 20:36:26

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-12-18T14:36:14', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '1bcce469-700f-44f2-8a72-83911624d11e'	System	18 Dec 2020 20:36:26
User entered 'No (N)'	System	18 Dec 2020 20:36:26

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-12-18T14:36:21', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '1bcce469-700f-44f2-8a72-83911624d11e' User entered '18 Dec 2020 14:36:21'	System	18 Dec 2020 20:36:26
	System	18 Dec 2020 20:36:26

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-12-24T13:51:15', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '394fc787-848a-4c8c-b4f7-e1846080e9e1'	System	24 Dec 2020 19:51:27
User entered 'No (N)'	System	24 Dec 2020 19:51:27

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-12-24T13:51:19', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '394fc787-848a-4c8c-b4f7-e1846080e9e1'	System	24 Dec 2020 19:51:27
User entered 'No (N)'	System	24 Dec 2020 19:51:27

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2020-12-24T13:51:24', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '394fc787-848a-4c8c-b4f7-e1846080e9e1' User entered '24 Dec 2020 13:51:24'	System	24 Dec 2020 19:51:27
	System	24 Dec 2020 19:51:27

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-01-02T10:57:17', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f3daba59-e975-4a3d-84f0-eaa422f83a71'	System	02 Jan 2021 16:57:31
User entered 'No (N)'	System	02 Jan 2021 16:57:31

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-01-02T10:57:21', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f3daba59-e975-4a3d-84f0-eaa422f83a71'	System	02 Jan 2021 16:57:31
User entered 'No (N)'	System	02 Jan 2021 16:57:31

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-01-02T10:57:25', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'f3daba59-e975-4a3d-84f0-eaa422f83a71' User entered '02 Jan 2021 10:57:25'	System	02 Jan 2021 16:57:31

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-01-07T14:54:05', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'be05517d-e449-48fd-b4c2-6cc76e68c45f'	System	07 Jan 2021 20:54:18
User entered 'No (N)'	System	07 Jan 2021 20:54:18

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-01-07T14:54:09', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'be05517d-e449-48fd-b4c2-6cc76e68c45f'	System	07 Jan 2021 20:54:18
User entered 'No (N)'	System	07 Jan 2021 20:54:18

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-01-07T14:54:14', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'be05517d-e449-48fd-b4c2-6cc76e68c45f'	System	07 Jan 2021 20:54:18
User entered '07 Jan 2021 14:54:14'	System	07 Jan 2021 20:54:18

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-01-17T13:58:06', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '34836994-3cce-41ce-a2b8-0a8b129deac2'	System	17 Jan 2021 19:58:20
User entered 'No (N)'	System	17 Jan 2021 19:58:20

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-01-17T13:58:10', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '34836994-3cce-41ce-a2b8-0a8b129deac2'	System	17 Jan 2021 19:58:20
User entered 'No (N)'	System	17 Jan 2021 19:58:20

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-01-17T13:58:16', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '34836994-3cce-41ce-a2b8-0a8b129deac2'	System	17 Jan 2021 19:58:20
User entered '17 Jan 2021 13:58:16'	System	17 Jan 2021 19:58:20

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-01-22T09:33:51', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '8f842ee1-c3fc-43d5-a7d5-baf53ea1cfee'	System	22 Jan 2021 15:34:37
User entered 'Yes (Y)'	System	22 Jan 2021 15:34:37

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-01-22T09:33:59', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '8f842ee1-c3fc-43d5-a7d5-baf53ea1cfee'	System	22 Jan 2021 15:34:37
User entered 'No (N)'	System	22 Jan 2021 15:34:37

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-01-22T09:34:05', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '8f842ee1-c3fc-43d5-a7d5-baf53ea1cfee'	System	22 Jan 2021 15:34:37
User entered 'No (N)'	System	22 Jan 2021 15:34:37

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-01-22T09:34:13', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '8f842ee1-c3fc-43d5-a7d5-baf53ea1cfee'	System	22 Jan 2021 15:34:37
User entered 'Yes (Y)'	System	22 Jan 2021 15:34:37

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-01-22T09:34:20', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '8f842ee1-c3fc-43d5-a7d5-baf53ea1cfee'	System	22 Jan 2021 15:34:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Jan 2021 15:34:37

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-01-22T09:34:26', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '8f842ee1-c3fc-43d5-a7d5-baf53ea1cfee'	System	22 Jan 2021 15:34:37
User entered '22 Jan 2021 09:34:26'	System	22 Jan 2021 15:34:37

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-01-30T07:47:46', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '001bf1d5-0ab8-4fe8-a4bb-d6ec25fe8125'	System	30 Jan 2021 13:47:56
User entered 'No (N)'	System	30 Jan 2021 13:47:56

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-01-30T07:47:50', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '001bf1d5-0ab8-4fe8-a4bb-d6ec25fe8125'	System	30 Jan 2021 13:47:56
User entered 'No (N)'	System	30 Jan 2021 13:47:56

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-01-30T07:47:54', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '001bf1d5-0ab8-4fe8-a4bb-d6ec25fe8125' User entered '30 Jan 2021 07:47:54'	System	30 Jan 2021 13:47:56
	System	30 Jan 2021 13:47:56

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-02-08T11:24:06', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '4c5dc46b-b14c-4eeb-b6b5-f97e039b5130'	System	08 Feb 2021 17:24:18
User entered 'No (N)'	System	08 Feb 2021 17:24:18

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-02-08T11:24:10', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '4c5dc46b-b14c-4eeb-b6b5-f97e039b5130'	System	08 Feb 2021 17:24:18
User entered 'No (N)'	System	08 Feb 2021 17:24:18

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-02-08T11:24:15', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '4c5dc46b-b14c-4eeb-b6b5-f97e039b5130'	System	08 Feb 2021 17:24:18
User entered '08 Feb 2021 11:24:15'	System	08 Feb 2021 17:24:18

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-02-12T15:55:10', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '01b540c1-3d1a-4fa9-8758-537830e80cf0'	System	12 Feb 2021 21:55:26
User entered 'No (N)'	System	12 Feb 2021 21:55:26

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-02-12T15:55:14', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '01b540c1-3d1a-4fa9-8758-537830e80cf0'	System	12 Feb 2021 21:55:26
User entered 'No (N)'	System	12 Feb 2021 21:55:26

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-02-12T15:55:21', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '01b540c1-3d1a-4fa9-8758-537830e80cf0'	System	12 Feb 2021 21:55:26
User entered '12 Feb 2021 15:55:21'	System	12 Feb 2021 21:55:26

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-02-18T19:11:34', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '6d3db92d-80c6-4983-a0d1-3e46504b0eda'	System	19 Feb 2021 01:11:53
User entered 'No (N)'	System	19 Feb 2021 01:11:53

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-02-18T19:11:38', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '6d3db92d-80c6-4983-a0d1-3e46504b0eda'	System	19 Feb 2021 01:11:53
User entered 'No (N)'	System	19 Feb 2021 01:11:53

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-02-18T19:11:48', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '6d3db92d-80c6-4983-a0d1-3e46504b0eda' User entered '18 Feb 2021 19:11:48'	System	19 Feb 2021 01:11:53

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-02-26T10:05:47', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'e9a11a29-7e9e-433b-adf9-94b3a0dcfe45'	System	26 Feb 2021 16:06:00
User entered 'No (N)'	System	26 Feb 2021 16:06:00

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-02-26T10:05:50', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'e9a11a29-7e9e-433b-adf9-94b3a0dcfe45'	System	26 Feb 2021 16:06:00
User entered 'No (N)'	System	26 Feb 2021 16:06:00

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-02-26T10:05:55', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'e9a11a29-7e9e-433b-adf9-94b3a0dcfe45'	System	26 Feb 2021 16:06:00
User entered '26 Feb 2021 10:05:55'	System	26 Feb 2021 16:06:00

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-03-05T09:49:45-06:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '545fbb62-2562-426e-86fd-62f9b2c8e72e'	System	05 Mar 2021 15:50:44
User entered 'No (N)'	System	05 Mar 2021 15:50:44

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-03-05T09:50:12-06:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '545fbb62-2562-426e-86fd-62f9b2c8e72e'	System	05 Mar 2021 15:50:44
User entered 'Yes (Y)'	System	05 Mar 2021 15:50:44

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-03-05T09:50:22-06:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '545fbb62-2562-426e-86fd-62f9b2c8e72e'	System	05 Mar 2021 15:50:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Mar 2021 15:50:44

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-03-05T09:50:31-06:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '545fbb62-2562-426e-86fd-62f9b2c8e72e' User entered '05 Mar 2021 09:50:31'	System	05 Mar 2021 15:50:44
	System	05 Mar 2021 15:50:44

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-03-13T10:11:33-06:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'a945f8cd-0184-48dd-b35f-76a59e6178f9' User entered 'No (N)'	System	13 Mar 2021 16:11:44
	System	13 Mar 2021 16:11:44

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-03-13T10:11:37-06:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'a945f8cd-0184-48dd-b35f-76a59e6178f9'	System	13 Mar 2021 16:11:44
User entered 'No (N)'	System	13 Mar 2021 16:11:44

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-03-13T10:11:42-06:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'a945f8cd-0184-48dd-b35f-76a59e6178f9' User entered '13 Mar 2021 10:11:42'	System	13 Mar 2021 16:11:44
	System	13 Mar 2021 16:11:44

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-03-18T08:31:19-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'deba0eaf-04a1-4ef7-99c4-1f0aa596ee35'	System	18 Mar 2021 13:32:07
User entered 'Yes (Y)'	System	18 Mar 2021 13:32:07

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-03-18T08:31:24-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'deba0eaf-04a1-4ef7-99c4-1f0aa596ee35'	System	18 Mar 2021 13:32:07
User entered 'No (N)'	System	18 Mar 2021 13:32:07

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-03-18T08:31:28-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'deba0eaf-04a1-4ef7-99c4-1f0aa596ee35'	System	18 Mar 2021 13:32:07
User entered 'No (N)'	System	18 Mar 2021 13:32:07

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-03-18T08:31:37-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'deba0eaf-04a1-4ef7-99c4-1f0aa596ee35'	System	18 Mar 2021 13:32:07
User entered 'Yes (Y)'	System	18 Mar 2021 13:32:07

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-03-18T08:31:47-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'deba0eaf-04a1-4ef7-99c4-1f0aa596ee35'	System	18 Mar 2021 13:32:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Mar 2021 13:32:07

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-03-18T08:31:56-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'deba0eaf-04a1-4ef7-99c4-1f0aa596ee35'	System	18 Mar 2021 13:32:07
User entered '18 Mar 2021 08:31:56'	System	18 Mar 2021 13:32:07

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-01T08:55:02-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0341ebb9-0791-47d9-bd2f-b48fa9c32dae' User entered 'Yes (Y)'	System	01 Apr 2021 13:55:52

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-01T08:55:12-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0341ebb9-0791-47d9-bd2f-b48fa9c32dae' User entered 'No (N)'	System	01 Apr 2021 13:55:52

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-01T08:55:17-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0341ebb9-0791-47d9-bd2f-b48fa9c32dae' User entered 'No (N)'	System	01 Apr 2021 13:55:52

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-01T08:55:27-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0341ebb9-0791-47d9-bd2f-b48fa9c32dae'	System	01 Apr 2021 13:55:52
User entered 'Yes (Y)'	System	01 Apr 2021 13:55:52

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-01T08:55:36-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0341ebb9-0791-47d9-bd2f-b48fa9c32dae'	System	01 Apr 2021 13:55:52
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Apr 2021 13:55:52

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-01T08:55:41-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '0341ebb9-0791-47d9-bd2f-b48fa9c32dae'	System	01 Apr 2021 13:55:52
User entered '01 Apr 2021 08:55:41'	System	01 Apr 2021 13:55:52

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-08T12:40:18-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'bc8ac1b1-311f-4133-8676-a0bd145929a0' User entered 'Yes (Y)'	System	08 Apr 2021 17:40:48

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-08T12:40:23-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'bc8ac1b1-311f-4133-8676-a0bd145929a0'	System	08 Apr 2021 17:40:48
User entered 'No (N)'	System	08 Apr 2021 17:40:48

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-08T12:40:27-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'bc8ac1b1-311f-4133-8676-a0bd145929a0' User entered 'No (N)'	System	08 Apr 2021 17:40:48

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-08T12:40:34-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'bc8ac1b1-311f-4133-8676-a0bd145929a0' User entered 'No (N)'	System	08 Apr 2021 17:40:48

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-08T12:40:43-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: 'bc8ac1b1-311f-4133-8676-a0bd145929a0'	System	08 Apr 2021 17:40:48
User entered '08 Apr 2021 12:40:43'	System	08 Apr 2021 17:40:48

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-16T09:09:19-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '8c1e86f7-5516-4208-9e4a-0d2287d6a3f9' User entered 'No (N)'	System	16 Apr 2021 14:09:38
	System	16 Apr 2021 14:09:38

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-16T09:09:23-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '8c1e86f7-5516-4208-9e4a-0d2287d6a3f9'	System	16 Apr 2021 14:09:38
User entered 'No (N)'	System	16 Apr 2021 14:09:38

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-16T09:09:32-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '8c1e86f7-5516-4208-9e4a-0d2287d6a3f9' User entered '16 Apr 2021 09:09:32'	System	16 Apr 2021 14:09:38
	System	16 Apr 2021 14:09:38

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-26T08:52:41-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '27c96a6a-a1f7-4792-b08a-108c8d7fbfdd'	System	26 Apr 2021 13:52:54
User entered 'No (N)'	System	26 Apr 2021 13:52:54

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-26T08:52:45-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '27c96a6a-a1f7-4792-b08a-108c8d7fbfdd'	System	26 Apr 2021 13:52:54
User entered 'No (N)'	System	26 Apr 2021 13:52:54

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-26T08:52:50-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '27c96a6a-a1f7-4792-b08a-108c8d7fbfdd'	System	26 Apr 2021 13:52:54
User entered '26 Apr 2021 08:52:50'	System	26 Apr 2021 13:52:54

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-30T10:10:26-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '84f2e1ba-653f-4d4b-9705-1287718d741b' User entered 'No (N)'	System	30 Apr 2021 15:10:42
	System	30 Apr 2021 15:10:42

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-30T10:10:30-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '84f2e1ba-653f-4d4b-9705-1287718d741b' User entered 'No (N)'	System	30 Apr 2021 15:10:42

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-04-30T10:10:37-05:00', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '84f2e1ba-653f-4d4b-9705-1287718d741b' User entered '30 Apr 2021 10:10:37'	System	30 Apr 2021 15:10:42
	System	30 Apr 2021 15:10:42

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:45:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 06:16:04

US3782162

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:45:13

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:59:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-03-03T13:20:44', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '85e087a7-a64c-4fa9-8d41-bf82ad5ec416'	System	03 Mar 2021 19:21:03
User entered 'No (N)'	System	03 Mar 2021 19:21:03

US3782162

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:45:13

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:59:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (989ecb69765dc1e1)', Time: '2021-03-03T13:20:54', User OID: 'PatientReportedOutcome (US3782162)', ODM File OID: '85e087a7-a64c-4fa9-8d41-bf82ad5ec416'	System	03 Mar 2021 19:21:03
User entered '03 Mar 2021 13:20:54'	System	03 Mar 2021 19:21:03

US3782162

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	04 Dec 2020 15:35:55

US3782162

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '4 Dec 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	04 Dec 2020 15:35:55

US3782162

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	04 Dec 2020 15:35:55

US3782162

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4) Carlton Griffin (b) (4) (b) (4)	04 Dec 2020 15:35:55

US3782162

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	04 Dec 2020 15:36:02

US3782162

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:58
User entered 'I'	System	04 Dec 2020 15:36:02

US3782162

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:49
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	08 Jan 2021 16:19:15

US3782162

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:49
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '8 Jan 2021'	Carlton Griffin (b) (4)	08 Jan 2021 16:19:15

US3782162

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:49
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	08 Jan 2021 16:19:15

US3782162

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:49
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4) Carlton Griffin (b) (4)	08 Jan 2021 16:19:15

US3782162

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:49
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	08 Jan 2021 16:19:21

US3782162

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:49
User entered 'I'	System	08 Jan 2021 16:19:21

US3782162

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:49
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	09 Feb 2021 19:17:28

US3782162

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:49
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered '9 Feb 2021'	(b) (4) Carlton Griffin (b) (4)	09 Feb 2021 19:17:28

US3782162

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:49
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4)	09 Feb 2021 19:17:28

US3782162

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:49
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered empty.	(b) (4) Carlton Griffin (b) (4)	09 Feb 2021 19:17:28

US3782162

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:49
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	09 Feb 2021 19:17:34

US3782162

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:49
User entered 'I'	System	09 Feb 2021 19:17:34

US3782162

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	30 Apr 2021 16:56:10
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:21:23
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	05 Mar 2021 16:39:35

US3782162

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:56:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
	(b) (4)	
User entered '5 Mar 2021'	Carlton Griffin (b) (4)	05 Mar 2021 16:39:35
	(b) (4)	

US3782162

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	30 Apr 2021 16:56:10
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:21:23
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4) (b) (4)	05 Mar 2021 16:39:35

US3782162

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:45:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	30 Apr 2021 16:56:10
User signature succeeded.	Spyros Kalams (b) (4) [REDACTED]	09 Apr 2021 01:21:23
User entered empty.	Carlton Griffin (b) (4) [REDACTED]	05 Mar 2021 16:39:35

US3782162

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:56:10
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	05 Mar 2021 16:39:27
	(b) (4)	

US3782162

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:56:10
User entered 'I'	System	05 Mar 2021 16:39:27

US3782162

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	09 Apr 2021 15:44:43
	(b) (4)	

US3782162

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered '9 Apr 2021'	Carlton Griffin (b) (4)	09 Apr 2021 15:44:43
	(b) (4)	

US3782162

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'Clinic (Clinic)'	Carlton Griffin (b) (4)	09 Apr 2021 15:44:43
	(b) (4)	

US3782162

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	09 Apr 2021 15:44:43

US3782162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	09 Apr 2021 15:44:56
	(b) (4)	

US3782162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	28 Apr 2021 21:43:21
User entered empty.	Carlton Griffin (b) (4) (b) (4)	09 Apr 2021 15:44:56

US3782162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	28 Apr 2021 21:43:21
User entered empty.	Carlton Griffin (b) (4) (b) (4)	09 Apr 2021 15:44:56

US3782162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 15:44:56

US3782162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	28 Apr 2021 21:43:21
User entered empty.	Carlton Griffin (b) (4) (b) (4)	09 Apr 2021 15:44:56

US3782162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	28 Apr 2021 21:43:21
User entered empty.	Carlton Griffin (b) (4) (b) (4)	09 Apr 2021 15:44:56

US3782162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	28 Apr 2021 21:43:21
User entered empty.	Carlton Griffin (b) (4) (b) (4)	09 Apr 2021 15:44:56

US3782162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	28 Apr 2021 21:43:21
User entered empty.	Carlton Griffin (b) (4) (b) (4)	09 Apr 2021 15:44:56

US3782162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 15:44:56

US3782162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	28 Apr 2021 21:43:21
User entered empty.	Carlton Griffin (b) (4) (b) (4)	09 Apr 2021 15:44:56

US3782162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 15:44:56

US3782162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	28 Apr 2021 21:43:21
User entered empty.	Carlton Griffin (b) (4) (b) (4)	09 Apr 2021 15:44:56

US3782162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 15:44:56

US3782162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	28 Apr 2021 21:43:21
User entered empty.	Carlton Griffin (b) (4) (b) (4)	09 Apr 2021 15:44:56

US3782162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:45:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 15:44:56

US3782162

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	09 Apr 2021 15:45:02
	(b) (4)	

US3782162

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:45:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered '9 Apr 2021'	Carlton Griffin (b) (4)	09 Apr 2021 15:45:02
	(b) (4)	

US3782162

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	09 Apr 2021 15:48:04
	(b) (4)	

US3782162

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered '9 Apr 2021'	Carlton Griffin (b) (4)	09 Apr 2021 15:48:04
	(b) (4)	

US3782162

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	28 Apr 2021 21:43:21
User entered '10:47'	Carlton Griffin (b) (4) (b) (4)	09 Apr 2021 15:48:04

US3782162

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '9 Apr 2021 10:47'	System	09 Apr 2021 15:48:04

US3782162

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	09 Apr 2021 15:45:06
	(b) (4)	

US3782162

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:45:13

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 15:45:06

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	08 Jan 2021 16:12:33

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '8 Jan 2021'	(b) (4) Carlton Griffin (b) (4)	08 Jan 2021 16:12:33
	(b) (4)	

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Clinic (Clinic)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	08 Jan 2021 16:12:33

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:45:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 16:12:33

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:13

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '8 Jan 2021'	(b) (4) Carlton Griffin (b) (4) (b) (4)	08 Jan 2021 16:12:48

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:13

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:51:44

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:13

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	08 Jan 2021 16:12:48

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:13

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:51:44

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:13

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '8 Jan 2021'	(b) (4) Carlton Griffin (b) (4) (b) (4)	08 Jan 2021 16:12:48

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:13

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Carlton Griffin (b) (4)	08 Jan 2021 16:12:48

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:13

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 14:25:06
User entered 'mRNA-1273 (mRNA-1273)'	Carlton Griffin (b) (4) (b) (4)	08 Jan 2021 16:12:48

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:13

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 14:25:06
User entered 'mRNA-1273 (mRNA-1273)'	Carlton Griffin (b) (4) (b) (4)	08 Jan 2021 16:12:48

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:13

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	08 Jan 2021 16:12:48

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:13

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User entered empty.	System	08 Jan 2021 16:12:48

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:45:13

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User entered empty.	System	08 Jan 2021 16:12:48

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	08 Jan 2021 16:13:01

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '8 Jan 2021'	(b) (4) Carlton Griffin (b) (4) (b) (4)	08 Jan 2021 16:13:01

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '09:57'	(b) (4) Carlton Griffin (b) (4) (b) (4)	08 Jan 2021 16:13:01

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:45:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User entered '8 Jan 2021 09:57'	System	08 Jan 2021 16:13:01

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:45:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	08 Jan 2021 16:13:12

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:45:13

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '8 Jan 2021'	(b) (4) Carlton Griffin (b) (4) (b) (4)	08 Jan 2021 16:13:12

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:45:13

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '09:59'	(b) (4) Carlton Griffin (b) (4) (b) (4)	08 Jan 2021 16:13:12

US3782162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:45:13

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:41
User entered '8 Jan 2021 09:59'	System	08 Jan 2021 16:13:12

US3782162

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:45:13

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:30:21
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	09 Oct 2020 17:29:45

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:40:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:23:21
User entered 'USA-US125-2020-mRNA-1273-P301000001'	System	12 Oct 2020 13:23:17
User entered 'New'	(b) (4), (b) (6)	12 Oct 2020 13:23:17

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:40:24
User coded data point as SOC: Cardiac disorders, HLG: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute coronary syndrome, LLT: Acute coronary syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:11:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 21:11:41
User closed query 'PV Query: Please confirm the name of the event as the DS reported the event as acute coronary syndrome.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 14:57:07
Query 'PV Query: Please confirm the name of the event as the DS reported the event as acute coronary syndrome.' answered with 'updated to match the DS report ' (Site from Safety).	Carlton Griffin (b) (4) (b) (4)	02 Nov 2020 16:14:01
Data point term sent to Coder	System	02 Nov 2020 16:13:39
Coding entries removed.	Carlton Griffin (b) (4) (b) (4)	02 Nov 2020 16:13:24
User entered 'acute coronary syndrome' reason for change: Per Query Resolution	Carlton Griffin (b) (4) (b) (4)	02 Nov 2020 16:13:24
User opened query 'PV Query: Please confirm the name of the event as the DS reported the event as acute coronary syndrome.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:05:36
User coded data point as SOC: Cardiac disorders, HLG: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Chest pain - cardiac - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 16:25:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 16:25:10
Data point term sent to Coder	System	26 Oct 2020 15:58:18
User closed query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain, unknown etiology, etc). ' (Site from System).	System	26 Oct 2020 15:58:15

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Adverse event](#)

Audit	User	Time (GMT)
Query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain, unknown etiology, etc). ' answered with 'updated- thanks' (Site from System). Data point term sent to Coder Coding entries removed.	Carlton Griffin (b) (4) (b) (4)	26 Oct 2020 15:58:15
	System	26 Oct 2020 15:58:14
	Carlton Griffin (b) (4) (b) (4)	26 Oct 2020 15:58:05
User entered 'CARDIAC CHEST PAIN' reason for change: Per Query Resolution	Carlton Griffin (b) (4) (b) (4)	26 Oct 2020 15:58:05
User opened query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain, unknown etiology, etc). ' (Site from System).	Coder Import (b) (4) (b) (4)	25 Oct 2020 16:45:35
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 17:58:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 17:58:30
Data point term sent to Coder	System	09 Oct 2020 17:57:20
User entered 'chest pain'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:40:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:40:32
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:40:37
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:40:42
User entered '21 Sep 2020'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:40:44
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:40:48
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:40:51
User entered '21 Sep 2020'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:40:53
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:40:58
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:41:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:41:10
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:41:11
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:41:13
User entered 'I'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:41:14
User entered '21 Sep 2020'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:41:16
User entered '24 Sep 2020'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:41:18
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:41:21
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:41:23
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:41:24
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:41:28
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:41:42
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:41:50
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:42:01
User entered 'None (NONE)'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

None

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:42:09
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
Query 'Per DM CLR-RQ; Site's response noted. However, the corresponding ConMed does not match the dates of this AE. Please review and update to record the medication given as treatment for this AE within this time frame as appropriate. Otherwise, clarify.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Dec 2020 22:05:13
User opened query 'Per DM CLR-RQ; Site's response noted. However, the corresponding ConMed does not match the dates of this AE. Please review and update to record the medication given as treatment for this AE within this time frame as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Dec 2020 22:01:54
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:33:29
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'con med added and started after the participant's hospitalization. indication for medication is "coronary artery disease" since he was diagnosed with this. ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	11 Nov 2020 17:20:10
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 07:00:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:42:11
User entered 'I'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:33:33
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with '2 concomitant procedures recorded during the time that the participant was hospitalized as shown above in hospitalization admission and discharge dates. the actual AE event only lasted for one day since it was originally chest pain occurrence ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	11 Nov 2020 17:19:17
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 07:00:03
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:42:13
User entered '1'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:42:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:42:32
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User closed query 'Per DM CLR: Narrative indicates that the subject had EKG. However, there is no corresponding ConProc record that match the information. Please update to record the procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:16:00
Query 'Per DM CLR: Narrative indicates that the subject had EKG. However, there is no corresponding ConProc record that match the information. Please update to record the procedure as appropriate. Otherwise, clarify.' answered with 'EKG is considered a diagnostic test not a procedure' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	02 Jan 2021 19:09:48
User opened query 'Per DM CLR: Narrative indicates that the subject had EKG. However, there is no corresponding ConProc record that match the information. Please update to record the procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Dec 2020 22:07:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:42:53
User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 19:00:40
User closed query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 19:00:31
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 19:00:20

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 18:59:45
User closed query 'PV Query: The case narrative mentions history of CAD/CABG. If CABG is considered MH, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 18:59:32
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 18:59:09
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'sent; thanks' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 19:59:13
Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' answered with 'unknown; can only speculate due to scheduling and patient's comorbidities; no documentation of reason' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 19:57:38
Query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Troponin < 0.01 and 0.02, D-dimer 0.34; labs included in medical records being sent' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 19:57:16

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'meds and procedures are appropriately added to the relevant forms; adding nuclear stress test' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 19:55:51
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'all negative - included in medical records being sent' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 19:55:13
Query 'PV Query: The case narrative mentions history of CAD/CABG. If CABG is considered MH, please add to MH eCRF.' answered with 'CABG is surgical history; we have a note on our source that he had this - but it isn't medical history' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 19:54:46
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:55:48
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:55:41
User opened query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:55:31
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:55:13

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:55:03
User opened query 'PV Query: The case narrative mentions history of CAD/CABG. If CABG is considered MH, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:54:55
User entered '5 minutes of chest pain only but went to hospital due to hx of CAD/CABG. Troponin, EKG, D-dimer all negative. LHC with patent stents and stable coronary anatomy.'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 17:57:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:45:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:43:04
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:37
User entered 'USA-US125-2020-mRNA-1273-P301000004'	System	27 Oct 2020 12:59:33
User entered 'New'	(b) (4), (b) (6)	27 Oct 2020 12:59:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:43:06
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Chest pain - cardiac - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 16:25:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 16:25:34
Data point term sent to Coder	System	26 Oct 2020 15:59:18
User closed query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' (Site from System).	System	26 Oct 2020 15:58:38
Query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' answered with 'updated thanks' (Site from System).	Carlton Griffin (b) (4) (b) (4)	26 Oct 2020 15:58:38
Coding entries removed.	Carlton Griffin (b) (4) (b) (4)	26 Oct 2020 15:58:30
User entered 'CARDIAC CHEST PAIN' reason for change: Per Query Resolution	Carlton Griffin (b) (4) (b) (4)	26 Oct 2020 15:58:30
User opened query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' (Site from System).	Coder Import (b) (4) (b) (4)	25 Oct 2020 16:45:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 12:29:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 12:29:40
Data point term sent to Coder	System	19 Oct 2020 12:28:18
User entered 'chest pain'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:43:08
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:43:11
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:43:24
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:43:35
User entered '14 Oct 2020'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:43:41
User entered empty.	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User entered empty.	System	19 Oct 2020 12:27:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:43:45
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:43:48
User entered '14 Oct 2020'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:43:51
User entered empty.	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User entered empty.	System	19 Oct 2020 12:27:53

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:43:56
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:44:00
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:44:11
User entered '0'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:44:13
User entered '0'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:44:18
User entered '0'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:44:25
User entered empty.	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:50:49
User entered empty.	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:44:27
User entered empty.	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:50:53
User entered empty.	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:50:54
User entered '0'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:50:56
User entered '0'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:50:58
User entered '0'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:50:59
User entered 'Not Related (NOT RELATED)'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:51:01
User entered 'Not Related (NOT RELATED)'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:51:03
User entered 'None (NONE)'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:51:06
User entered '0'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:51:08
User entered 'I'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:51:10
User entered '0'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:51:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:51:15
User entered empty.	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:51:24
User entered 'participant stated on safety call that he had a small episode of chest pain. took nitroglycerin and chest pain resolved. (b) (6) is following up with his cardiologist this week.'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User entered '0'	System	19 Oct 2020 12:27:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33
User entered 'l'	System	19 Oct 2020 12:27:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:45:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Apr 2021 18:25:08
Data hard unlocked.	(b) (4), (b) (6)	04 Apr 2021 21:25:15
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:24:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:34:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:16
User entered	System	25 Jan 2021 02:22:06
'USA-US125-2021-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	25 Jan 2021 02:22:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of ANGINA noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:37:55
	(b) (4), (b) (6)	02 Mar 2021 20:34:45
Query 'Per DM CLR: Please confirm if this AE is a worsening of ANGINA noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' answered with 'not worsening angina. this was another episode of angina completely unrelated to the first episode that happened. ' (Site from DM). User opened query 'Per DM CLR: Please confirm if this AE is a worsening of ANGINA noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	26 Feb 2021 13:57:45
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of ANGINA noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 06:33:27
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 18:08:14
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'not assessed for potential COVID-19 infection by the study clinic as this subject was not having reportable COVID-19 symptoms ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	23 Feb 2021 17:12:08
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 17:09:44

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Chest pain - cardiac - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 16:54:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 16:54:01
	(b) (4)	
Data point term sent to Coder	System	22 Jan 2021 16:53:35
User entered 'cardiac chest pain'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:34:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:34:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:35:03
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:35:48
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '21 Jan 2021'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:35:52
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 16:53:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:35:58
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Carlton Griffin (b) (4)	25 Jan 2021 18:53:58
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:36:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '21 Jan 2021' reason for change: New Information	Carlton Griffin (b) (4)	25 Jan 2021 18:53:58
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:36:04
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 16:53:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:36:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:36:14
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:36:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:36:22
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:36:38
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	29 Jan 2021 09:59:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'information is given. will update discharge date when known' (Site from System).	Carlton Griffin (b) (4)	22 Jan 2021 16:54:32
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	22 Jan 2021 16:53:22
User entered 'I'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:36:45
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '22 Jan 2021' reason for change: Data Entry Error	Carlton Griffin (b) (4)	25 Jan 2021 15:57:49
	(b) (4)	
User entered '21 Jan 2021'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:36:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '23 Jan 2021' reason for change: New Information	Carlton Griffin (b) (4)	25 Jan 2021 15:57:49
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:38:22
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	25 Jan 2021 15:57:49
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		25 Jan 2021 15:57:49
User entered 'No (N)' reason for change: New Information	Carlton Griffin (b) (4)	25 Jan 2021 15:57:49
	(b) (4)	
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	22 Jan 2021 16:53:22
User entered 'Unknown (UNK)'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:38:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:38:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:38:31
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:38:33
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:38:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:38:38
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:38:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:38:52
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:38:54
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'I'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:38:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:39:03
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Carlton Griffin (b) (4)	25 Jan 2021 18:53:58
New Information	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:39:08
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:39:09
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 17:01:23
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 17:01:17
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'no results available ' (Site from Safety).	Carlton Griffin (b) (4)	01 Feb 2021 20:13:38
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'nasopharyngeal swab on 22Jan2021 during hospital admission result was negative ' (Site from Safety).	Carlton Griffin (b) (4)	01 Feb 2021 20:11:25
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 17:21:43

US3782162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 17:18:07
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Participant entered in his e diary on day 138 that he had contact with his healthcare provider since the last time he had completed his questionnaire. Call to participant. Participant's wife answered the phone and shared brief details about participant's change in health. She reports on the night of 21Jan2021 participant began having episodes of chest pain. His wife reports that participant had chest pain that was unrelieved by three doses of nitroglycerin. He was admitted to the hospital yesterday evening and a workup is in progress. She reports that the participant did not have a heart attack and he is currently stable. Will plan follow-up with participant early next week.'	Carlton Griffin (b) (4)	22 Jan 2021 16:53:22

US3782162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Jan 2021 16:53:22

US3782162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Jan 2021 16:53:22

US3782162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:45:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Jan 2021 16:53:22

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin melanomas (excl ocular), PT: Malignant melanoma, LLT: Melanoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Mar 2021 16:08:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 16:08:40
Data point term sent to Coder	System	18 Mar 2021 15:53:03
User entered 'melanoma right arm'	Carlton Griffin (b) (4)	18 Mar 2021 15:52:36
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	18 Mar 2021 15:52:36
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:21:23
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 15:52:36

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	18 Mar 2021 15:52:36
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
	(b) (4)	
User entered '12 Mar 2021'	Carlton Griffin (b) (4)	18 Mar 2021 15:52:36
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:21:23
User entered empty.	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 15:52:36

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 15:52:36

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:21:23
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 15:52:36

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:21:23
User entered empty.	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 15:52:36

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:21:23
User entered empty.	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 15:52:36

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 15:52:36

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Carlton Griffin (b) (4)	18 Mar 2021 15:52:36
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	18 Mar 2021 15:52:36
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:21:23
User entered '0'	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 15:52:36

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:21:23
User entered '0'	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 15:52:36

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	18 Mar 2021 15:52:36
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:21:23
User entered empty.	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 15:52:36

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:21:23
User entered empty.	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 15:52:36

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:21:23
User entered empty.	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 15:52:36

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:21:23
User entered empty.	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 15:52:36

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	18 Mar 2021 15:52:36
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	18 Mar 2021 15:52:36
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:21:23
User entered '0'	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 15:52:36

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
User entered 'Not Related (NOT RELATED)'	(b) (4) Carlton Griffin (b) (4)	18 Mar 2021 15:52:36
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Carlton Griffin (b) (4)	18 Mar 2021 15:52:36
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Carlton Griffin (b) (4)	18 Mar 2021 15:52:36

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:21:23
User entered '0'	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 15:52:36

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:21:23
User entered '0'	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 15:52:36

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:21:23
User entered 'I'	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 15:52:36

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Carlton Griffin (b) (4)	18 Mar 2021 15:52:36

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:21:23
User entered empty.	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 15:52:36

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	09 Apr 2021 01:21:23
User entered empty.	Carlton Griffin (b) (4) (b) (4)	18 Mar 2021 15:52:36

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Mar 2021 15:52:36

US3782162

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:45:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Mar 2021 15:52:36

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:45:13

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:52:43
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:06:54

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Sep 2020 19:10:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 19:10:54
Data point term sent to Coder	System	08 Sep 2020 19:09:29
User entered 'Acetaminophen'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:09:26

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:09:26
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Back Pain'	Jenna Caserta (b) (4)	08 Sep 2020 19:09:26
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered '325'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:09:26

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'mg (mg)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:09:26

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:09:26

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'four times daily (QID)'	Jenna Caserta (b) (4)	08 Sep 2020 19:09:26
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:09:26

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Oral (ORAL)'	Jenna Caserta (b) (4)	08 Sep 2020 19:09:26
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:09:26

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'un UNK 2017'	Jenna Caserta (b) (4)	08 Sep 2020 19:09:26
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:09:26

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:09:26

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:09:26

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:09:26

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	08 Sep 2020 19:09:26

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 19:09:26

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 19:09:26

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:09:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 19:12:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 19:12:00
Data point term sent to Coder User entered 'ASA'	System Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:10:32 08 Sep 2020 19:10:17

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:09:18
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:10:17

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:09:21
User entered 'CAD'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:10:17

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:09:25
User entered '325'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:10:17

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:09:27
User entered 'mg (mg)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:10:17

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:09:30
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:10:17

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:09:36
User entered 'once daily (QD)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:10:17

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:09:39
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:10:17

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:09:45
User entered 'Oral (ORAL)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:10:17

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:09:49
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:10:17

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:09:51
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:10:17

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:09:53
User entered 'I'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:10:17

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:10:09
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:10:17

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:10:11
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:10:17

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:10:20
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:10:17

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 19:10:17

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 19:10:17

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 19:10:17

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 18:41:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 18:41:21
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	05 Oct 2020 18:40:37 05 Oct 2020 18:39:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 19:12:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 19:12:48
Data point term sent to Coder User entered 'Atorvastatin'	System Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:11:33 08 Sep 2020 19:11:22

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:11:22
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Hyperlipidemia'	Jenna Caserta (b) (4)	08 Sep 2020 19:11:22
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered '40'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:11:22

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'mg (mg)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:11:22

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:11:22

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'once daily (QD)'	Jenna Caserta (b) (4)	08 Sep 2020 19:11:22
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:11:22

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User closed query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please review and correct as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:16:33
Query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please review and correct as appropriate.' answered with 'data entry error corrected' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 18:40:00
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 18:39:50
User opened query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please review and correct as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 12:41:21
User entered 'Topical (TOPICAL)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:11:22

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:11:22

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:11:22

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'I'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:11:22

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:11:22

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:11:22
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:11:22
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 19:11:22

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 19:11:22

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 19:11:22

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPA AND DOPA DERIVATIVES, PRODUCT: CARBIDOPA;LEVODOPA, PRODUCTSYNONYM: CARBIDOPA/LEVODOPA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Sep 2020 19:13:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 19:13:50
Data point term sent to Coder	System	08 Sep 2020 19:13:37
User entered 'Carbidopa/Levodopa'	Jenna Caserta (b) (4)	08 Sep 2020 19:12:38
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:12:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'Tremors'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:12:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '25/100'	Jenna Caserta (b) (4)	08 Sep 2020 19:12:38
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'mg (mg)'	Jenna Caserta (b) (4)	08 Sep 2020 19:12:38
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:12:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'three times daily (TID)'	Jenna Caserta (b) (4)	08 Sep 2020 19:12:38
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:12:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Oral (ORAL)'	Jenna Caserta (b) (4)	08 Sep 2020 19:12:38
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:12:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:12:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'I'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:12:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 19:12:38
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:12:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:12:38
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	08 Sep 2020 19:12:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 19:12:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 19:12:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Sep 2020 19:15:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 19:15:56
Data point term sent to Coder	System	08 Sep 2020 19:14:38
User entered 'Miralax'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:13:44

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:13:44

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'Constipation'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:13:44

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered '17'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:13:44

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'g (g)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:13:44

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:13:44

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'as needed (PRN)'	Jenna Caserta (b) (4)	08 Sep 2020 19:13:44
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:13:44

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Oral (ORAL)'	Jenna Caserta (b) (4)	08 Sep 2020 19:13:44
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:13:44

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:13:44

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'I'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:13:44

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:13:44

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:13:44

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:13:44

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:13:44

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:13:44

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:13:44

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:11:06
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 19:18:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 19:18:50
	(b) (4)	
Data point term sent to Coder	System	08 Sep 2020 19:17:42
User entered 'Finasteride'	Jenna Caserta (b) (4)	08 Sep 2020 19:16:52
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:11:07
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:16:52

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:11:10
User entered 'BPH'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:16:52

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:11:17
User entered '5'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:16:52

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:11:21
User entered 'mg (mg)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:16:52

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:11:24
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:16:52

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:11:27
User entered 'once daily (QD)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:16:52

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:11:29
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:16:52

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:11:31
User entered 'Oral (ORAL)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:16:52

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:11:34
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:16:52

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:11:40
User entered 'un UNK 2015'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:16:52

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:11:41
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:16:52

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:11:45
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:16:52

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:11:48
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:16:52

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:11:51
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:16:52

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 19:16:52

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 19:16:52

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 19:16:52

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:09
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Sep 2020 19:19:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 19:19:51
Data point term sent to Coder	System	08 Sep 2020 19:18:44
User entered 'Gabapentin'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:18:02

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:09
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:18:02

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:09
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Back Pain'	Jenna Caserta (b) (4)	08 Sep 2020 19:18:02

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:09
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '800'	Jenna Caserta (b) (4)	08 Sep 2020 19:18:02

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:09
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'mg (mg)'	Jenna Caserta (b) (4)	08 Sep 2020 19:18:02

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:09
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:18:02

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:09
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'three times daily (TID)'	Jenna Caserta (b) (4)	08 Sep 2020 19:18:02

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:09
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:18:02

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:09
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Oral (ORAL)'	Jenna Caserta (b) (4)	08 Sep 2020 19:18:02

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:09
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:18:02

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:09
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'un UNK 2017'	Jenna Caserta (b) (4)	08 Sep 2020 19:18:02

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:09
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4)	08 Sep 2020 19:18:02

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:09
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)' reason for change: New Information	Carlton Griffin (b) (4)	06 Nov 2020 16:15:08
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 19:18:02

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:09
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '22 Oct 2020' reason for change: New Information	(b) (4)	
	Carlton Griffin (b) (4)	06 Nov 2020 16:15:08
User entered empty.	(b) (4)	
	Jenna Caserta (b) (4)	08 Sep 2020 19:18:02
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:09
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:18:02

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:09
User entered '3'	System	08 Sep 2020 19:18:02

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:09
User entered '1'	System	08 Sep 2020 19:18:02

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:09
User entered '804 (804)'	System	08 Sep 2020 19:18:02

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:12:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 19:19:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 19:19:51
Data point term sent to Coder User entered 'Losartan'	System Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:18:44 08 Sep 2020 19:18:39

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:12:39
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:18:39

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:12:45
User entered 'Hypertension'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:18:39

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:12:52
User entered '50'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:18:39

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:12:53
User entered 'mg (mg)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:18:39

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:12:57
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:18:39

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:13:01
User entered 'once daily (QD)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:18:39

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:13:04
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:18:39

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:13:05
User entered 'Oral (ORAL)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:18:39

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:13:07
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:18:39

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:13:09
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:18:39

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:13:12
User entered 'I'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:18:39

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:13:14
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:18:39

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:13:15
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:18:39

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:13:17
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:18:39

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 19:18:39

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 19:18:39

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 19:18:39

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Sep 2020 19:28:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 19:28:47
Data point term sent to Coder	System	08 Sep 2020 19:28:10
User entered 'Omeprazole'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:27:51

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:27:51

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'GERD'	Jenna Caserta (b) (4)	08 Sep 2020 19:27:51
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '20'	Jenna Caserta (b) (4)	08 Sep 2020 19:27:51
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'mg (mg)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:27:51

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:27:51

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'once daily (QD)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:27:51

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:27:51

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Oral (ORAL)'	Jenna Caserta (b) (4)	08 Sep 2020 19:27:51
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:27:51

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:27:51

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:13

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'I'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:27:51

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 19:27:51
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:27:51

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:27:51
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 19:27:51

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 19:27:51

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 19:27:51

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: BARBITURATES AND DERIVATIVES, PRODUCT: PRIMIDONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Sep 2020 06:26:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 06:26:39
Data point term sent to Coder	System	08 Sep 2020 19:30:15
User entered 'Primidone'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:29:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:29:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Tremor'	Jenna Caserta (b) (4)	08 Sep 2020 19:29:38
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered '50'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:29:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'mg (mg)'	Jenna Caserta (b) (4)	08 Sep 2020 19:29:38
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:29:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'twice daily (BID)'	Jenna Caserta (b) (4)	08 Sep 2020 19:29:38
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:29:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Oral (ORAL)'	Jenna Caserta (b) (4)	08 Sep 2020 19:29:38
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:29:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:29:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'I'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:29:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:29:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:29:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:29:38
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Sep 2020 19:29:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 19:29:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 19:29:38

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:13:53
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 19:31:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 19:31:49
Data point term sent to Coder User entered 'Flomax'	System Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:31:16 08 Sep 2020 19:30:28

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:13:55
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:30:28

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered 'BPH'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:30:28

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:14:01
User entered '0.4'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:30:28

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:14:04
User entered 'mg (mg)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:30:28

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:14:08
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:30:28

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:14:06
User entered 'twice daily (BID)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:30:28

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:14:10
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:30:28

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:14:12
User entered 'Oral (ORAL)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:30:28

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:14:13
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:30:28

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:14:16
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:30:28

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:14:20
User entered 'I'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:30:28

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:14:24
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:30:28

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:14:26
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:30:28

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:14:29
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:30:28

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Sep 2020 19:30:28

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 19:30:28

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 19:30:28

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Sep 2020 20:07:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 20:07:53
Data point term sent to Coder	System	08 Sep 2020 20:06:57
User entered 'Vitamin D'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 20:06:40

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 20:06:40

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'general health'	Jenna Caserta (b) (4)	08 Sep 2020 20:06:40
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:16:46
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'dosage updated' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	06 Oct 2020 14:27:48
User entered '5,000' reason for change: Per Query Resolution	Carlton Griffin (b) (4) (b) (4)	06 Oct 2020 14:27:42
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 12:42:02
User entered '1'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 20:06:40

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'IU (IU)' reason for change: Per Query Resolution	Carlton Griffin (b) (4)	06 Oct 2020 14:27:42
	(b) (4)	
User entered 'tablet (TABLET)'	Jenna Caserta (b) (4)	08 Sep 2020 20:06:40
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 20:06:40

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'once daily (QD)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 20:06:40

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 20:06:40

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Oral (ORAL)'	Jenna Caserta (b) (4)	08 Sep 2020 20:06:40
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 20:06:40

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '8 Sep 2020'	Jenna Caserta (b) (4)	08 Sep 2020 20:06:40
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:13

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 20:06:40

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 20:06:40

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 20:06:40

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 20:06:40
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:06:40

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 20:06:40

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 20:06:40

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
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.	(b) (4) Coder Import (b) (4)	06 Oct 2020 14:30:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:30:10
Data point term sent to Coder	System	06 Oct 2020 14:29:08
User entered 'multivitamin'	Carlton Griffin (b) (4) (b) (4)	06 Oct 2020 14:29:04

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:25:47
Query 'Per DM CLR: 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) (b) (4)	02 Dec 2020 16:52:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Carlton Griffin (b) (4) (b) (4)	02 Dec 2020 16:52:10
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 05:38:25
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	06 Oct 2020 14:29:04

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'general health'	Carlton Griffin (b) (4)	06 Oct 2020 14:29:04
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '1'	Carlton Griffin (b) (4)	06 Oct 2020 14:29:04
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'tablet (TABLET)'	Carlton Griffin (b) (4)	06 Oct 2020 14:29:04
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	06 Oct 2020 14:29:04
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'once daily (QD)'	Carlton Griffin (b) (4)	06 Oct 2020 14:29:04
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	06 Oct 2020 14:29:04
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4)	06 Oct 2020 14:29:04
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	06 Oct 2020 14:29:04
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'UN UNK 2000'	Carlton Griffin (b) (4)	06 Oct 2020 14:29:04
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	06 Oct 2020 14:29:04
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	06 Oct 2020 14:29:04
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	06 Oct 2020 14:29:04
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	06 Oct 2020 14:29:04
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 14:29:04

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 14:29:04

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 14:29:04

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:23
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:14:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 18:06:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 18:06:33
Data point term sent to Coder	System	09 Oct 2020 18:05:33
User entered 'metoprolol'	(b) (4), (b) (6)	09 Oct 2020 18:05:08

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:23
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:14:56
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 18:05:08

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:23
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:14:57
User entered 'coronary artery disease'	(b) (4), (b) (6)	09 Oct 2020 18:05:08

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:23
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:15:00
User entered '12.5'	(b) (4), (b) (6)	09 Oct 2020 18:05:08

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:23
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:15:22
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Oct 2020 18:05:08

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:23
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:15:27
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:05:08

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:23
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:15:35
User entered 'once daily (QD)'	(b) (4), (b) (6)	09 Oct 2020 18:05:08

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:23
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:15:42
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:05:08

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:23
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:15:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Oct 2020 18:05:08

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:23
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:15:48
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:05:08

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:23
User closed query 'Per DM CLR: This Con Med was added on 24 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 14:18:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
Query 'Per DM CLR: This Con Med was added on 24 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'see AE form' (Site from DM).	Carlton Griffin (b) (4)	06 Jan 2021 18:46:15
User opened query 'Per DM CLR: This Con Med was added on 24 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 11:00:07
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:15:50
User entered '24 Sep 2020'	(b) (4), (b) (6)	09 Oct 2020 18:05:08

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:23
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:15:53
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 18:05:08

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:23
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:15:55
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	30 Oct 2020 20:32:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 18:05:08

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:23
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:16:13
User entered '27 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	30 Oct 2020 20:32:49
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:05:08

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:23
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:16:17
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 18:05:08

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:23
User entered '1'	System	09 Oct 2020 18:05:08

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:23
User entered '1'	System	09 Oct 2020 18:05:08

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:23
User entered '804 (804)'	System	09 Oct 2020 18:05:08

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:27
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Oct 2020 20:47:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Oct 2020 20:47:30
Data point term sent to Coder	System	10 Oct 2020 20:46:19
User entered 'Acetaminophen'	(b) (4), (b) (6)	10 Oct 2020 20:45:55

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:27
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Oct 2020 20:45:55

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:27
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'post-vaccination symptom prophylaxis'	(b) (4) (b) (4), (b) (6)	10 Oct 2020 20:45:55

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:27
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '1000'	(b) (4) (b) (4), (b) (6)	10 Oct 2020 20:45:55

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:27
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Oct 2020 20:45:55

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:13

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:27
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Oct 2020 20:45:55

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:27
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	10 Oct 2020 20:45:55

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:27
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Oct 2020 20:45:55

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:27
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Oct 2020 20:45:55

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:13

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:27
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Oct 2020 20:45:55

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:27
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	10 Oct 2020 20:45:55

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:27
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Oct 2020 20:45:55

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:27
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Oct 2020 20:45:55

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:27
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	10 Oct 2020 20:45:55

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:27
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Oct 2020 20:45:55

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:27
User entered empty.	System	10 Oct 2020 20:45:55

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:27
User entered empty.	System	10 Oct 2020 20:45:55

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:27
User entered empty.	System	10 Oct 2020 20:45:55

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:38
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 18:40:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 18:40:43
Data point term sent to Coder	System	02 Dec 2020 16:53:05
Coding entries removed.	Carlton Griffin (b) (4)	02 Dec 2020 16:53:00
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:16:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 12:34:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 12:34:45
Data point term sent to Coder	System	19 Oct 2020 12:33:22
User entered 'nitroglycerin'	Carlton Griffin (b) (4)	19 Oct 2020 12:32:43

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:38
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:16:29
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:32:43

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:38
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:41:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:26:14
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' answered with 'updated to reflect AE term' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	02 Dec 2020 16:53:08
DataPoint Un-verified.	Carlton Griffin (b) (4) (b) (4)	02 Dec 2020 16:53:00
User entered 'CARDIAC CHEST PAIN' reason for change: Data Entry Error	Carlton Griffin (b) (4) (b) (4)	02 Dec 2020 16:53:00
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 05:38:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:16:31
User entered 'chest pain'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:32:43

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:38
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:16:36
User entered '0.4'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:32:43

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:38
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:16:37
User entered 'mg (mg)'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:32:43

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:38
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:16:40
User entered empty.	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:32:43

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:38
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:16:42
User entered 'once (ONCE)'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:32:43

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:38
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:16:43
User entered empty.	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:32:43

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:38
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:16:45
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:32:43

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:38
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:17:12
User entered empty.	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:32:43

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:38
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:17:16
User entered '14 Oct 2020'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:32:43

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:38
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:17:20
User entered '0'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:32:43

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:38
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:17:23
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:32:43

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:38
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:17:26
User entered '14 Oct 2020'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:32:43

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:38
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:17:28
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:32:43

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:38
User entered empty.	System	19 Oct 2020 12:32:43

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:38
User entered empty.	System	19 Oct 2020 12:32:43

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:38
User entered empty.	System	19 Oct 2020 12:32:43

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
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)	30 Oct 2020 20:29:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 20:29:55
Data point term sent to Coder	System	30 Oct 2020 20:29:07
User entered 'influenza vaccine'	(b) (4), (b) (6)	30 Oct 2020 20:29:00

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:00

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'influenza prophylaxis'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:00

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0.5'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:00

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:00

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:13

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:00

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:00

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:00

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:00

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:00

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:32:12
User entered '28 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:29:00

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:00

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:00

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:32:12
User entered '28 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:29:00

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:29:00

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:43
User entered empty.	System	30 Oct 2020 20:29:00

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:43
User entered empty.	System	30 Oct 2020 20:29:00

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:01:43
User entered empty.	System	30 Oct 2020 20:29:00

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:17:39
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 01:06:13
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 01:06:13
	(b) (4)	
Data point term sent to Coder	System	30 Oct 2020 20:32:41
User entered 'metoprolol'	(b) (4), (b) (6)	30 Oct 2020 20:31:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:41:13
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 20:31:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:17:43
User entered 'coronary artery disease'	(b) (4), (b) (6)	30 Oct 2020 20:31:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:17:47
User entered '25'	(b) (4), (b) (6)	30 Oct 2020 20:31:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:17:52
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Oct 2020 20:31:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:17:54
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:31:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:17:59
User entered 'three times daily (TID)'	(b) (4), (b) (6)	30 Oct 2020 20:31:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:18:01
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:31:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:18:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Oct 2020 20:31:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:18:08
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:31:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query ' Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 14:19:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
Query ' Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' answered with 'see AE form ' (Site from DM).	(b) (4) Carlton Griffin (b) (4)	06 Jan 2021 18:45:56
User opened query ' Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 11:00:52
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:18:10
User entered '28 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:31:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:18:12
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:31:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:18:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:31:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:18:17
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:31:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:18:19
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 20:31:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Oct 2020 20:31:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 20:31:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Oct 2020 20:31:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 17:25:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 17:25:58
Data point term sent to Coder	System	15 Mar 2021 17:25:07
Coding entries removed.	(b) (4), (b) (6)	15 Mar 2021 17:24:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:41:20
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 17:04:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 17:04:02
Data point term sent to Coder	System	22 Jan 2021 17:02:49
User entered 'nitroglycerin'	(b) (4), (b) (6)	22 Jan 2021 17:02:27

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:41:22
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 17:02:27

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:21:08
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:35:33
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' answered with 'clarified; however, the query page states this query is 129 days overdue - please note this is not correct.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 17:25:29
DataPoint Un-verified.	(b) (4), (b) (6)	15 Mar 2021 17:24:55
Signature has been broken.	(b) (4), (b) (6)	15 Mar 2021 17:24:55
User entered 'CHEST PAIN (cardiac)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Mar 2021 17:24:55
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 03:51:00
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:42:30
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:30:06

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User entered 'chest pain'	(b) (4), (b) (6)	22 Jan 2021 17:02:27

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:42:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '0.4'	(b) (4), (b) (6)	22 Jan 2021 17:02:27

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:42:38
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Jan 2021 17:02:27

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:42:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 17:02:27

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:42:42
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'as needed (PRN)'	(b) (4), (b) (6)	22 Jan 2021 17:02:27

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:42:44
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 17:02:27

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:42:47
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Jan 2021 17:02:27

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:42:48
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 17:02:27

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:42:50
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '21 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 17:02:27

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:42:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Jan 2021 17:02:27

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:42:55
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 17:02:27

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:43:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 17:02:27

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:43:05
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Jan 2021 17:02:27

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 17:02:27

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 17:02:27

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 17:02:27

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:43:20
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: ISOSORBIDE MONONITRATE, PRODUCTSYNONYM: IMDUR - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Jan 2021 18:47:06
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	27 Jan 2021 18:47:06
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\202003.		
Data point term sent to Coder	System	27 Jan 2021 18:45:51
User entered 'imdur'	Carlton Griffin (b) (4)	27 Jan 2021 18:45:46
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:43:21
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	27 Jan 2021 18:45:46
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:43:23
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered 'angina'	Carlton Griffin (b) (4)	27 Jan 2021 18:45:46
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:43:25
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered '30'	Carlton Griffin (b) (4)	27 Jan 2021 18:45:46
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:43:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	27 Jan 2021 18:45:46
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:43:31
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	27 Jan 2021 18:45:46
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:43:33
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered 'once daily (QD)'	Carlton Griffin (b) (4)	27 Jan 2021 18:45:46
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:13

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:43:35
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	27 Jan 2021 18:45:46
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:43:36
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4)	27 Jan 2021 18:45:46
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:43:38
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	27 Jan 2021 18:45:46
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:43:40
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered '23 Jan 2021'	Carlton Griffin (b) (4)	27 Jan 2021 18:45:46
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:43:44
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	27 Jan 2021 18:45:46
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:43:46
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	27 Jan 2021 18:45:46
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:44:00
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	27 Jan 2021 18:45:46
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:44:06
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	27 Jan 2021 18:45:46
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Jan 2021 18:45:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Jan 2021 18:45:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Jan 2021 18:45:46

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: RANOLAZINE, PRODUCTSYNONYM: RANEXA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Jan 2021 18:48:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 18:48:08
Data point term sent to Coder	System	27 Jan 2021 18:46:53
User entered 'ranexa'	Carlton Griffin (b) (4) (b) (4)	27 Jan 2021 18:46:10

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	27 Jan 2021 18:46:10
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered 'angina'	Carlton Griffin (b) (4)	27 Jan 2021 18:46:10
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered '500'	Carlton Griffin (b) (4)	27 Jan 2021 18:46:10
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	27 Jan 2021 18:46:10
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	27 Jan 2021 18:46:10
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered 'twice daily (BID)'	Carlton Griffin (b) (4)	27 Jan 2021 18:46:10
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	19 Feb 2021 23:32:58
User entered empty.	Carlton Griffin (b) (4) (b) (4)	27 Jan 2021 18:46:10

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4)	27 Jan 2021 18:46:10
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	19 Feb 2021 23:32:58
User entered empty.	Carlton Griffin (b) (4) (b) (4)	27 Jan 2021 18:46:10

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered '23 Jan 2021'	Carlton Griffin (b) (4)	27 Jan 2021 18:46:10
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	27 Jan 2021 18:46:10
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	27 Jan 2021 18:46:10
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	27 Jan 2021 18:46:10
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	27 Jan 2021 18:46:10
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Jan 2021 18:46:10

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Jan 2021 18:46:10

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Jan 2021 18:46:10

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:02:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User coded data point as ATC: VARIOUS, ATC: INVESTIGATIONAL DRUG, PRODUCT: INVESTIGATIONAL DRUG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Jan 2021 12:01:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Jan 2021 12:01:18
Data point term sent to Coder	System	29 Jan 2021 19:45:08
User entered 'zoledronic acid/placebo'	Carlton Griffin (b) (4) (b) (4)	29 Jan 2021 19:44:21

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:02:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	29 Jan 2021 19:44:21

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:02:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered 'fracture prophylaxis'	(b) (4) Carlton Griffin (b) (4) (b) (4)	29 Jan 2021 19:44:21

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:02:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered '5'	(b) (4) Carlton Griffin (b) (4) (b) (4)	29 Jan 2021 19:44:21

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:02:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered 'mg (mg)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	29 Jan 2021 19:44:21

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:02:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered empty.	(b) (4) Carlton Griffin (b) (4)	29 Jan 2021 19:44:21

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:02:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered 'once (ONCE)'	(b) (4) Carlton Griffin (b) (4)	29 Jan 2021 19:44:21

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:13

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:02:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered empty.	(b) (4) Carlton Griffin (b) (4)	29 Jan 2021 19:44:21

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:02:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Carlton Griffin (b) (4)	29 Jan 2021 19:44:21

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:02:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered empty.	(b) (4) Carlton Griffin (b) (4) (b) (4)	29 Jan 2021 19:44:21

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:02:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered '20 Jan 2021'	(b) (4) Carlton Griffin (b) (4) (b) (4)	29 Jan 2021 19:44:21

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:02:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered '0'	(b) (4) Carlton Griffin (b) (4) (b) (4)	29 Jan 2021 19:44:21

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:02:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	29 Jan 2021 19:44:21

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:02:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered '20 Jan 2021'	(b) (4) Carlton Griffin (b) (4) (b) (4)	29 Jan 2021 19:44:21

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:02:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:58
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	29 Jan 2021 19:44:21

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:02:12
User entered empty.	System	29 Jan 2021 19:44:21

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:02:12
User entered empty.	System	29 Jan 2021 19:44:21

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:02:12
User entered empty.	System	29 Jan 2021 19:44:21

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ANESTHETICS, GENERAL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Apr 2021 14:40:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:40:55
Data point term sent to Coder	System	09 Apr 2021 15:14:00
User entered 'general anesthesia'	Carlton Griffin (b) (4) (b) (4)	09 Apr 2021 15:13:14

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	09 Apr 2021 15:13:14
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'r. arm wide excision of melanoma and r. axilla sentinel lymph node biopsy'	Carlton Griffin (b) (4)	09 Apr 2021 15:13:14
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'UNKNOWN'	Carlton Griffin (b) (4)	09 Apr 2021 15:13:14
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'Other (OTHER)'	Carlton Griffin (b) (4)	09 Apr 2021 15:13:14
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'UNKNOWN'	Carlton Griffin (b) (4)	09 Apr 2021 15:13:14
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'unknown (UNKNOWN)'	Carlton Griffin (b) (4)	09 Apr 2021 15:13:14
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	28 Apr 2021 21:43:21
User entered empty.	Carlton Griffin (b) (4) (b) (4)	09 Apr 2021 15:13:14

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4)	09 Apr 2021 15:13:14
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	09 Apr 2021 15:13:14
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered '02 Apr 2021'	Carlton Griffin (b) (4)	09 Apr 2021 15:13:14
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	09 Apr 2021 15:13:14
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	09 Apr 2021 15:13:14
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered '02 Apr 2021'	Carlton Griffin (b) (4)	09 Apr 2021 15:13:14
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	09 Apr 2021 15:13:14
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 15:13:14

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 15:13:14

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 15:13:14

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Apr 2021 09:07:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 09:07:54
Data point term sent to Coder	System	09 Apr 2021 17:33:36
User entered 'oxycodone'	Carlton Griffin (b) (4) (b) (4)	09 Apr 2021 17:32:41

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	09 Apr 2021 17:32:41
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'r. arm wide excision of melanoma and r. axilla sentinel lymph node biopsy'	Carlton Griffin (b) (4)	09 Apr 2021 17:32:41
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered '5'	Carlton Griffin (b) (4)	09 Apr 2021 17:32:41
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	09 Apr 2021 17:32:41
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	09 Apr 2021 17:32:41
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'as needed (PRN)'	Carlton Griffin (b) (4)	09 Apr 2021 17:32:41
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	09 Apr 2021 17:32:41
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4)	09 Apr 2021 17:32:41
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	09 Apr 2021 17:32:41
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered '02 Apr 2021'	Carlton Griffin (b) (4)	09 Apr 2021 17:32:41
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	09 Apr 2021 17:32:41
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	09 Apr 2021 17:32:41
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered '04 Apr 2021'	Carlton Griffin (b) (4)	09 Apr 2021 17:32:41
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	09 Apr 2021 17:32:41
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:32:41

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:32:41

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:32:41

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Apr 2021 17:35:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 17:35:42
Data point term sent to Coder	System	09 Apr 2021 17:34:42
User entered 'Heparin'	(b) (4), (b) (6)	09 Apr 2021 17:34:36

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:34:36

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered 'DVT prophylaxis'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:34:36

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered '5000'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:34:36

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:34:36

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:13

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'units'	(b) (4), (b) (6)	09 Apr 2021 17:34:36

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:34:36

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 17:34:36

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:34:36

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 17:34:36

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered '2 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:34:36

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 17:34:36

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:34:36

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered '2 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:34:36

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 17:34:36

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:34:36

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:34:36

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:34:36

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Apr 2021 17:37:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 17:37:51
Data point term sent to Coder	System	09 Apr 2021 17:36:44
User entered 'Cefazolin'	(b) (4), (b) (6)	09 Apr 2021 17:36:16

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 17:36:16

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered 'infection prophylaxis'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:36:16

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered '2'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:36:16

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'g (g)'	(b) (4), (b) (6)	09 Apr 2021 17:36:16

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 17:36:16

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:36:16

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:13

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 17:36:16

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:36:16

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 17:36:16

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered '2 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:36:16

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 17:36:16

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 17:36:16

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered '2 Apr 2021'	(b) (4), (b) (6)	09 Apr 2021 17:36:16

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 17:36:16

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:36:16

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:36:16

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:36:16

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:13

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Apr 2021 17:39:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 17:39:24
Data point term sent to Coder	System	09 Apr 2021 17:37:45
User entered 'zofran'	(b) (4), (b) (6)	09 Apr 2021 17:36:59

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:36:59

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered 'nausea prophylaxis'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:36:59

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered '4'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:36:59

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:36:59

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 17:36:59

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:36:59

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 17:36:59

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:36:59

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 17:36:59

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered '2 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:36:59

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:36:59

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:36:59

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered '2 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:36:59

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 17:36:59

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:36:59

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:36:59

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:45:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 17:36:59

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:45:13

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:53:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 17:57:36

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:45:13

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:06
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:55:26
User entered '23 Sep 2020'	(b) (4), (b) (6)	09 Oct 2020 17:58:13

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:45:13

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:06
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:55:28
User entered 'left heart catheterization'	(b) (4), (b) (6)	09 Oct 2020 17:58:13

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:06
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:55:30
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	09 Oct 2020 17:58:13

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:45:13

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:06
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:55:31
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 17:58:13

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:45:13

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:08
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:56:10
User entered '22 Sep 2020'	(b) (4), (b) (6)	20 Oct 2020 19:56:31

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:45:13

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:08
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:59:36
User entered 'nuclear stress test'	(b) (4), (b) (6)	20 Oct 2020 19:56:31

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:08
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:59:39
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	20 Oct 2020 19:56:31

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:45:13

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:08
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:59:41
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 19:56:31

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:45:13

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:12
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered '22 Oct 2020'	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:30:36

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:45:13

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:12
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:59:51
User entered 'colonoscopy'	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:30:36

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:12
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:59:53
User entered 'Other (OTHER)'	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:30:36

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:45:13

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:12
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:59:55
User entered 'routine'	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:30:36

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:45:13

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:15
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
User entered '12 Mar 2021'	(b) (4) Carlton Griffin (b) (4)	18 Mar 2021 16:24:03
	(b) (4)	

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:45:13

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:15
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
User entered 'skin biopsy right arm'	Carlton Griffin (b) (4)	18 Mar 2021 16:24:03

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:15
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
User entered 'Adverse Event (AE)'	(b) (4) Carlton Griffin (b) (4)	18 Mar 2021 16:24:03

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:45:13

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:15
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:21:23
User entered empty.	Carlton Griffin (b) (4)	18 Mar 2021 16:24:03

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:45:13

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered '02 Apr 2021'	Carlton Griffin (b) (4)	09 Apr 2021 15:03:08
	(b) (4)	

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:45:13

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'r. arm wide excision of melanoma and r. axilla lymph node biopsy'	Carlton Griffin (b) (4)	09 Apr 2021 15:03:08
	(b) (4)	

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:45:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered 'Adverse Event (AE)'	Carlton Griffin (b) (4)	09 Apr 2021 15:03:08
	(b) (4)	

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:45:13

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:21
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	09 Apr 2021 15:03:08
	(b) (4)	

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'USA-US125-2020-MRNA-1273-P301000001'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Yes (Y)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Yes (Y)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Spyros'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Kalams'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered '1161 21st Avenue South'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Nashville'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:28:30
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
DataPoint Un-verified.	System	25 Jan 2021 02:22:06
User entered empty.	System	25 Jan 2021 02:22:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:35:55
User entered 'Tennessee'	Carlton Griffin (b) (4)	10 Nov 2020 17:29:14
	(b) (4)	

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered '37232'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:57:45
User entered 'US'	System	12 Oct 2020 13:27:46

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '4'	System	03 Nov 2020 14:58:44
User entered '3'	System	27 Oct 2020 18:16:06
User entered '2'	System	21 Oct 2020 18:58:04
User entered '1'	System	12 Oct 2020 13:27:46

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'USA-US125-2020-MRNA-1273-P301000001'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Yes (Y)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Yes (Y)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Spyros'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Kalams'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered '1161 21st Avenue South'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Nashville'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:28:30
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
DataPoint Un-verified.	System	25 Jan 2021 02:22:06
User entered empty.	System	25 Jan 2021 02:22:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:35:55
User entered 'Tennessee'	Carlton Griffin (b) (4)	10 Nov 2020 17:29:14
	(b) (4)	

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered '37232'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:57:45
User entered 'US'	System	12 Oct 2020 13:27:46

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '4'	System	03 Nov 2020 14:58:44
User entered '3'	System	27 Oct 2020 18:16:06
User entered '2'	System	21 Oct 2020 18:58:04
User entered '1'	System	12 Oct 2020 13:27:46

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:45:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
User entered '12/Oct/2020 09:27'	System	12 Oct 2020 13:27:46

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:45:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:57:45
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 13:27:46

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'USA-US125-2020-MRNA-1273-P301000001'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Yes (Y)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Yes (Y)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Spyros'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Kalams'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered '1161 21st Avenue South'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Nashville'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:28:30
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
DataPoint Un-verified.	System	25 Jan 2021 02:22:06
User entered empty.	System	25 Jan 2021 02:22:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:35:55
User entered 'Tennessee'	Carlton Griffin (b) (4)	10 Nov 2020 17:29:14
	(b) (4)	

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered '37232'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:57:45
User entered 'US'	System	12 Oct 2020 13:27:46

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '4'	System	03 Nov 2020 14:58:44
User entered '3'	System	27 Oct 2020 18:16:06
User entered '2'	System	21 Oct 2020 18:58:04
User entered '1'	System	12 Oct 2020 13:27:46

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:45:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
User entered '21/Oct/2020 14:58'	System	21 Oct 2020 18:58:04

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:45:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 18:15:54
User entered 'I'	(b) (4), (b) (6)	21 Oct 2020 18:58:04

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'USA-US125-2020-MRNA-1273-P301000001'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Yes (Y)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Yes (Y)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Spyros'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Kalams'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered '1161 21st Avenue South'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Nashville'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:28:30
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
DataPoint Un-verified.	System	25 Jan 2021 02:22:06
User entered empty.	System	25 Jan 2021 02:22:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:35:55
User entered 'Tennessee'	Carlton Griffin (b) (4)	10 Nov 2020 17:29:14
	(b) (4)	

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered '37232'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:57:45
User entered 'US'	System	12 Oct 2020 13:27:46

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '4'	System	03 Nov 2020 14:58:44
User entered '3'	System	27 Oct 2020 18:16:06
User entered '2'	System	21 Oct 2020 18:58:04
User entered '1'	System	12 Oct 2020 13:27:46

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:45:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
User entered '27/Oct/2020 18:16'	System	27 Oct 2020 18:16:06

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:45:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 14:58:24
User entered 'I'	(b) (4), (b) (6)	27 Oct 2020 18:16:06

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'USA-US125-2020-MRNA-1273-P301000001'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Yes (Y)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Yes (Y)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'No (N)'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Spyros'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Kalams'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered '1161 21st Avenue South'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered 'Nashville'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:28:30
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
DataPoint Un-verified.	System	25 Jan 2021 02:22:06
User entered empty.	System	25 Jan 2021 02:22:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:35:55
User entered 'Tennessee'	Carlton Griffin (b) (4)	10 Nov 2020 17:29:14
	(b) (4)	

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 13:27:41
User entered '37232'	System	12 Oct 2020 13:23:17

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:57:45
User entered 'US'	System	12 Oct 2020 13:27:46

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '4'	System	03 Nov 2020 14:58:44
User entered '3'	System	27 Oct 2020 18:16:06
User entered '2'	System	21 Oct 2020 18:58:04
User entered '1'	System	12 Oct 2020 13:27:46

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:45:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
User entered '03/Nov/2020 09:58'	System	03 Nov 2020 14:58:44

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:45:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:35:55
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 14:58:44

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'USA-US125-2020-MRNA-1273-P301000004'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'No (N)'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'No (N)'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'No (N)'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'No (N)'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'No (N)'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'No (N)'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'No (N)'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'Spyros'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'Kalams'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered '1161 21st Avenue South'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'Nashville'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:33:03
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
DataPoint Un-verified.	System	25 Jan 2021 02:22:06
User entered empty.	System	25 Jan 2021 02:22:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:36:07
User entered 'Tennessee'	Carlton Griffin (b) (4)	10 Nov 2020 17:29:26
	(b) (4)	

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered '37232'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
User entered 'US'	System	27 Oct 2020 12:59:56

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'I'	(b) (4) System	27 Oct 2020 12:59:56

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'USA-US125-2020-MRNA-1273-P301000004'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'No (N)'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'No (N)'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'No (N)'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'No (N)'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'No (N)'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'No (N)'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'No (N)'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'Spyros'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'Kalams'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered '1161 21st Avenue South'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered 'Nashville'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:33:03
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
DataPoint Un-verified.	System	25 Jan 2021 02:22:06
User entered empty.	System	25 Jan 2021 02:22:06
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:36:07
User entered 'Tennessee'	Carlton Griffin (b) (4)	10 Nov 2020 17:29:26
	(b) (4)	

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 12:59:51
User entered '37232'	System	27 Oct 2020 12:59:33

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
User entered 'US'	System	27 Oct 2020 12:59:56

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'I'	(b) (4) System	27 Oct 2020 12:59:56

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:45:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
User entered '27/Oct/2020 08:59'	System	27 Oct 2020 12:59:56

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:45:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:07
User entered 'I'	(b) (4), (b) (6)	27 Oct 2020 12:59:56

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:33:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'USA-US125-2021-MRNA-1273-P301000001'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:33:35
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'Yes (Y)'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:33:40
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'No (N)'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:33:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'No (N)'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:33:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'Yes (Y)'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:33:57
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'No (N)'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:33:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'No (N)'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:34:01
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'No (N)'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:34:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'Spyros'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:34:04
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'Kalams'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:34:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered '1161 21st Avenue South'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:34:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'Nashville'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:34:13
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered '37232'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:34:15
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'US'	(b) (4) System	25 Jan 2021 02:22:40

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'I'	(b) (4) System	25 Jan 2021 02:22:40

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:33:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'USA-US125-2021-MRNA-1273-P301000001'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:33:35
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'Yes (Y)'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:33:40
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'No (N)'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:33:41
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'No (N)'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:33:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'Yes (Y)'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:33:57
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'No (N)'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:33:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'No (N)'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:34:01
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'No (N)'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:34:02
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'Spyros'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:34:04
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'Kalams'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:34:10
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered '1161 21st Avenue South'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:34:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered 'Nashville'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:34:13
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 02:22:31
User entered '37232'	System	25 Jan 2021 02:22:06

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:34:15
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'US'	(b) (4) System	25 Jan 2021 02:22:40

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:45:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
User entered 'I'	(b) (4) System	25 Jan 2021 02:22:40

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:45:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:34:21
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered '24/Jan/2021 21:22'	System	25 Jan 2021 02:22:40

US3782162

Folder: SAE USA-US125-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:45:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 20:34:23
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:30:06
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 02:22:40