

US3782162 (Prod: Vanderbilt University Medical Center)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:16:11

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US3782162

Form: Participant Creation

Generated On: 26 Nov 2020 11:16:11

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:16:11

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:11

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

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:11

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 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:16:11

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:16:11

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:11

Condition	HYPERTENSION
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:11

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:11

Condition	BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:11

Condition	GERD
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:11

Condition	BPH
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:11

Condition	TREMOR
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:11

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:11

Condition	SENSORY HEARING LOSS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:11

Condition	CONSTIPATION
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

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

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:11

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

Generated On: 26 Nov 2020 11:16:11

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

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

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Folder: Screening

Form: Risk of Exposure

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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

Generated On: 26 Nov 2020 11:16:11

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:11

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

Generated On: 26 Nov 2020 11:16:11

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:11

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	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 ☒ Axillary ☐ Other ☐
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)

Generated On: 26 Nov 2020 11:16:11

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	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 ☒ Axillary ☐ Other ☐
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

Generated On: 26 Nov 2020 11:16:11

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

Generated On: 26 Nov 2020 11:16:11

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

Generated On: 26 Nov 2020 11:16:11

Was the sample collected?

Yes ☒

No ☐

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

Generated On: 26 Nov 2020 11:16:11

Collection date (<i>dd MMM yyyy</i>)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	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

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:11

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:16:11

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:16:11

Yes ☐	
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: 26 Nov 2020 11:16:11

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 ☒

US3782162

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:11

Yes ☐	
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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

Yes ☐	
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: 26 Nov 2020 11:16:11

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 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:16:11

Yes ☐	
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: 26 Nov 2020 11:16:11

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 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:16:11

Yes ☐	
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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

Yes ☐	
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

Generated On: 26 Nov 2020 11:16:11

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

Generated On: 26 Nov 2020 11:16:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

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

Generated On: 26 Nov 2020 11:16:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

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

Generated On: 26 Nov 2020 11:16:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:11

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	9 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:11

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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)

Generated On: 26 Nov 2020 11:16:11

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 11:16:11

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

Generated On: 26 Nov 2020 11:16:11

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

Generated On: 26 Nov 2020 11:16:11

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	9 OCT 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 11:16:11

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

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

Yes ☐	
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: 26 Nov 2020 11:16:11

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 ☒

US3782162

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:16:11

Yes ☐	
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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

Yes ☐	
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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

Yes ☐	
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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

		Yes ☐
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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

		Yes ☐
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: 26 Nov 2020 11:16:11

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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

Generated On: 26 Nov 2020 11:16:11

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

Generated On: 26 Nov 2020 11:16:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

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

Generated On: 26 Nov 2020 11:16:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

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

Generated On: 26 Nov 2020 11:16:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:11

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	6 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

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

US3782162

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:11

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

Generated On: 26 Nov 2020 11:16:11

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	6 NOV 2020
Collection time (<i>00:00-23:59</i>)	09:50 (24 HR)
Collection date and time (derived)	6 NOV 2020 09:50

US3782162

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:16:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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 ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 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: 26 Nov 2020 11:16:11

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 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: 26 Nov 2020 11:16:11

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:16:11

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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: 26 Nov 2020 11:16:11

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 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: 26 Nov 2020 11:16:11

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 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: 26 Nov 2020 11:16:11

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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: 26 Nov 2020 11:16:11

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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: 26 Nov 2020 11:16:11

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 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: 26 Nov 2020 11:16:11

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 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: 26 Nov 2020 11:16:11

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 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: 26 Nov 2020 11:16:11

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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: 26 Nov 2020 11:16:11

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 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: 26 Nov 2020 11:16:11

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 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: 26 Nov 2020 11:16:11

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 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: 26 Nov 2020 11:16:11

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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: 26 Nov 2020 11:16:11

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 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: 26 Nov 2020 11:16:11

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 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: 26 Nov 2020 11:16:11

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:16:11

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 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: 26 Nov 2020 11:16:11

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 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: 26 Nov 2020 11:16:11

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 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: 26 Nov 2020 11:16:11

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:16:11

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 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: 26 Nov 2020 11:16:11

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:16:11

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 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: 26 Nov 2020 11:16:11

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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

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: 26 Nov 2020 11:16:11

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:16:11

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:16:11

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

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 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: 26 Nov 2020 11:16:11

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 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: 26 Nov 2020 11:16:11

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 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: 26 Nov 2020 11:16:11

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:16:11

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:16:11

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 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: 26 Nov 2020 11:16:11

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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: 26 Nov 2020 11:16:11

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:16:11

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

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: 26 Nov 2020 11:16:11

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 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: 26 Nov 2020 11:16:11

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 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: 26 Nov 2020 11:16:11

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:16:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:16:11

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

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27 DEC 2021 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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03 JAN 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

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10 JAN 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

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17 JAN 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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

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24 JAN 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

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31 JAN 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

03 FEB 2022 00:01

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07 FEB 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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

17 FEB 2022 00:01

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21 FEB 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

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28 FEB 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

14 APR 2022 00:01

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18 APR 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

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25 APR 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

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02 MAY 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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09 MAY 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

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16 MAY 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 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: 26 Nov 2020 11:16:11

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

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30 MAY 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

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06 JUN 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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20 JUN 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

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27 JUN 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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30 JUN 2022 00:01

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04 JUL 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:16:11

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

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07 JUL 2022 00:01

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11 JUL 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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14 JUL 2022 00:01

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18 JUL 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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21 JUL 2022 00:01

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25 JUL 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

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01 AUG 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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04 AUG 2022 00:01

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08 AUG 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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11 AUG 2022 00:01

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15 AUG 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

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22 AUG 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

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29 AUG 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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

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01 SEP 2022 00:01

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05 SEP 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 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: 26 Nov 2020 11:16:11

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 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: 26 Nov 2020 11:16:11

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 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: 26 Nov 2020 11:16:11

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:16:11

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 11:16:11

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

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

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: 26 Nov 2020 11:16:11

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:16:11

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

[Patient Cloud Close Date & Time](#)

14 NOV 2022 23:59

US3782162

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

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 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:11

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3782162

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:16:11

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

US3782162

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:16:11

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3782162

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:16:11

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)

Generated On: 26 Nov 2020 11:16:11

AEID	USA-US125-2020-MRNA-1273-P30 1000001
Adverse event	ACUTE CORONARY SYNDROME
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	21 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
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 ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	21 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	24 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	339 of 2064

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:11

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

v6.020 DTW (1102)

340 of 2064

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

AEID	USA-US125-2020-MRNA-1273-P30 1000004
Adverse event	CARDIAC CHEST PAIN
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	14 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
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 ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	342 of 2064

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

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

v6.020 DTW (1102)

343 of 2064

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

Admitted to ICU Derived (CSA Programming Field Only)

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:16:11

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

Yes ☒

No ☐

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

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:11

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 ☐ Intramuscular ☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:11

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:11

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 ☐ Intramuscular ☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:11

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

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:11

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 ☐ Intramuscular ☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:16:11

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

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:11

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 ☐ Intramuscular ☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:11

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		
Start date completely unknown		True
Ongoing?		Yes ☒
		No ☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?		Yes ☐
		No ☒
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☒

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:11

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 ☐ Intramuscular ☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:11

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

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:11

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 ☐ Intramuscular ☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:16:11

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:11

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 ☐ Intramuscular ☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:11

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Ongoing?	Yes ☐
	No ☒
If not Ongoing, End date (dd MMM yyyy)	22 OCT 2020
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:11

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 ☐ Intramuscular ☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:11

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

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:11

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 ☐ Intramuscular ☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:11

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

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:11

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 ☐ Intramuscular ☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:16:11

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

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:11

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 ☐ Intramuscular ☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:11

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

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:11

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 ☐ Intramuscular ☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:11

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		8 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:11

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 ☐ Intramuscular ☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:11

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

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:11

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 ☐ Intramuscular ☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:16:11

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	24 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ☒
If not Ongoing, End date (dd MMM yyyy)	27 OCT 2020
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:16:11

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 ☐ Intraocular ☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:16:11

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		9 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		9 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:11

Name of Medication	NITROGLYCERIN
Prophylaxis	Yes ☐ No ☒
Indication	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 ☐ Intramuscular ☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:11

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		14 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:16:11

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 ☐ Intramuscular ☒

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:16:11

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		26 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		26 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:16:11

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 ☐ Intramuscular ☐

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:16:11

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:16:11

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:16:11

Procedure/Surgery date (<i>dd MMM yyyy</i>)	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

US3782162

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:16:11

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

US3782162

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:16:11

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

Generated On: 26 Nov 2020 11:16:11

SAEID	USA-US125-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	TENNESSEE
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)

Generated On: 26 Nov 2020 11:16:11

SAEID	USA-US125-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	TENNESSEE
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)

Generated On: 26 Nov 2020 11:16:11

SAEID	USA-US125-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	TENNESSEE
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)

Generated On: 26 Nov 2020 11:16:11

SAEID	USA-US125-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	TENNESSEE
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)

Generated On: 26 Nov 2020 11:16:11

SAEID	USA-US125-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	TENNESSEE
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

Generated On: 26 Nov 2020 11:16:11

SAEID	USA-US125-2020-MRNA-1273-P301000004
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	TENNESSEE
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)

Generated On: 26 Nov 2020 11:16:11

SAEID	USA-US125-2020-MRNA-1273-P301000004
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	TENNESSEE
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

Audit

US3782162 (Prod: Vanderbilt University Medical Center)

US3782162

Form: Participant Creation

Generated On: 26 Nov 2020 11:16:11

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3782162'	RWS_ENDPOINT ENDPOINT (b) (4) 	08 Sep 2020 18:09:27

US3782162

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:16:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:23:34

US3782162

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '08 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	08 Sep 2020 18:09:28

US3782162

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:23:34

US3782162

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:16:11

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	08 Sep 2020 18:23:34

US3782162

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:11

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1941'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	08 Sep 2020 18:09:29

US3782162

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:11

[Age](#)

Audit	User	Time (GMT)
User entered '78'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:11

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '78'	System	08 Sep 2020 18:24:45

US3782162

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:11

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:11

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:11

White

Audit	User	Time (GMT)
User entered '1'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:11

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:11

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:11

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:11

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:11

Unknown

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:16:11

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:24:08

US3782162

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:11

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:24:45

US3782162

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	08 Sep 2020 18:24:45

US3782162

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '2020'	System	08 Sep 2020 18:24:45

US3782162

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:11

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:24:45

US3782162

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:24:45

US3782162

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:11

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:24:45

US3782162

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:24:45

US3782162

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:11

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:24:45

US3782162

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	08 Sep 2020 18:09:28

US3782162

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:16:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:25:39

US3782162

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:25:39

US3782162

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:16:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:31:38

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (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) (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) (b) (4)	08 Sep 2020 19:03:21

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:03:21

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:03:21

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:03:21

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:11

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:03:21

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:03:21

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:03:21

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:03:21

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:03:21

US3782162

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:03:21

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: 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
	(b) (4)	

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:03:40

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:03:40

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:03:40

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:03:40

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:03:40

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:03:40

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:03:40

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:03:40

US3782162

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:03:40

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:11

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '2017'	System	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:04:09

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:11

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:04:31

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:04:31

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:04:31

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:04:31

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:04:31

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:04:31

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:04:31

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:04:31

US3782162

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:04:31

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:11

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:04:56

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:04:56

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:04:56

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:04:56

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:04:56

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	08 Sep 2020 19:04:56

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '2015'	System	08 Sep 2020 19:04:56

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:04:56

US3782162

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:04:56

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:11

Condition

Audit	User	Time (GMT)
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
	(b) (4)	

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:05:21

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:05:21

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:05:21

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:05:21

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:05:21

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:05:21

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:05:21

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:05:21

US3782162

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:05:21

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:11

[Condition](#)

Audit	User	Time (GMT)
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.	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 'Hyperlipidemia'	Jenna Caserta (b) (4)	08 Sep 2020 19:05:42
	(b) (4)	

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:05:42

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:05:42

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:05:42

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:05:42

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:05:42

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:05:42

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:05:42

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:05:42

US3782162

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:05:42

US3782162

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:11

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:05:56

US3782162

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:05:56

US3782162

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:05:56

US3782162

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:05:56

US3782162

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:05:56

US3782162

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:05:56

US3782162

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:05:56

US3782162

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:05:56

US3782162

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:05:56

US3782162

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:11

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:06:41

US3782162

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:06:41

US3782162

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:06:41

US3782162

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:06:41

US3782162

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:06:41

US3782162

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:06:41

US3782162

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:06:41

US3782162

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:06:41

US3782162

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 19:06:41

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '13:06'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '8 Sep 2020 13:06'	System	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '161.5' cm	Jenna Caserta (b) (4)	08 Sep 2020 18:45:55
DataPoint set to visible.	(b) (4) System	08 Sep 2020 18:25:39

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '76.9' kg	Jenna Caserta (b) (4)	08 Sep 2020 18:45:55
DataPoint set to visible.	(b) (4) System	08 Sep 2020 18:25:39

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 17:52:33
Query 'Data is required please update accordingly.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 16:10:10
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 16:09:52
User opened query 'Data is required please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:36:30
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 18:45:55

US3782162

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:32:30

US3782162

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:32:30

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '1'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:16:11

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:02:02

US3782162

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:16:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:25:24

US3782162

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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) (b) (4)	08 Sep 2020 18:25:24

US3782162

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:16:11

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:25:24

US3782162

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:16:11

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	08 Sep 2020 18:25:24

US3782162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '08 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	08 Sep 2020 18:19:59

US3782162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:11

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '190005'	RWS_ENDPOINT ENDPOINT (b) (4) 	08 Sep 2020 18:19:59

US3782162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	08 Sep 2020 18:19:59

US3782162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:11

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:33:17

US3782162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:11

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:33:17

US3782162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:33:17

US3782162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:11

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:33:17

US3782162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:11

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:33:17

US3782162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 11:16:11

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:16:11

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:16:11

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:16:11

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	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: 26 Nov 2020 11:16:11

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	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: 26 Nov 2020 11:16:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:16:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020' reason for change: Data Entry Error	(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 (1)

Generated On: 26 Nov 2020 11:16:11

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:06'	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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.0' C	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: 26 Nov 2020 11:16:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 11:16:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:16:11

Pulse (xxx)

Audit	User	Time (GMT)
User entered '98'	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: 26 Nov 2020 11:16:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '16'	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: 26 Nov 2020 11:16:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '141'	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: 26 Nov 2020 11:16:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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)	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)	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)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:16:11

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:16:11

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	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: 26 Nov 2020 11:16:11

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:16:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 13:23:13
User entered '8 Sep 2020'	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: 26 Nov 2020 11:16:11

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:13'	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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	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: 26 Nov 2020 11:16:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 11:16:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:16:11

Pulse (xxx)

Audit	User	Time (GMT)
User entered '81'	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: 26 Nov 2020 11:16:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '18'	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: 26 Nov 2020 11:16:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '123'	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: 26 Nov 2020 11:16:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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)	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)	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)	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 19:33:35

US3782162

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:11

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:47:27

US3782162

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:47:27

US3782162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:49:13

US3782162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:11

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:49:13

US3782162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:49:13

US3782162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 18:49:13

US3782162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '08 Sep 2020' reason for change: Data Entry Error	(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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '13:43'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:49:13

US3782162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:49:13

US3782162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	08 Sep 2020 18:49:13

US3782162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 18:49:13

US3782162

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:46:54

US3782162

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020' reason for change: Data Entry Error	(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: 26 Nov 2020 11:16:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:18'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:46:54

US3782162

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Sep 2020' reason for change: Data Entry Error	(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: 26 Nov 2020 11:16:11

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:16:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '13:21'	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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:16:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 18:47:08

US3782162

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 18:47:53

US3782162

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:16:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 18:47:53

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	10 Sep 2020 22:52:04
User entered '97.2'	System	10 Sep 2020 22:52:04

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	10 Sep 2020 22:52:04
User entered '10 Sep 2020 17:51'	System	10 Sep 2020 22:52:04

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	13 Sep 2020 13:12:08
User entered '97.6'	System	13 Sep 2020 13:12:08

US3782162

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	10 Sep 2020 00:16:37
User entered '09 Sep 2020 19:16'	System	10 Sep 2020 00:16:37

US3782162

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

HEADACHE

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:16:11

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:16:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

CHILLS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:16:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:16:11

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	15 Sep 2020 18:42:09

US3782162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Carlton Griffin (b) (4) (b) (4)	15 Sep 2020 18:42:09

US3782162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4) (b) (4)	15 Sep 2020 18:42:09

US3782162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Carlton Griffin (b) (4) (b) (4)	15 Sep 2020 18:42:09

US3782162

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	15 Sep 2020 18:42:13

US3782162

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 18:42:13

US3782162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	22 Sep 2020 20:51:59

US3782162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	Carlton Griffin (b) (4) (b) (4)	22 Sep 2020 20:51:59

US3782162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4) (b) (4)	22 Sep 2020 20:51:59

US3782162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Carlton Griffin (b) (4) (b) (4)	22 Sep 2020 20:51:59

US3782162

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	22 Sep 2020 20:52:03

US3782162

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 20:52:03

US3782162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	29 Sep 2020 17:49:59

US3782162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Carlton Griffin (b) (4) (b) (4)	29 Sep 2020 17:49:59

US3782162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4) (b) (4)	29 Sep 2020 17:49:59

US3782162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Carlton Griffin (b) (4) (b) (4)	29 Sep 2020 17:49:59

US3782162

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	29 Sep 2020 17:50:07

US3782162

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 17:50:07

US3782162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 17:43:02

US3782162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 17:43:02

US3782162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Oct 2020 17:43:02

US3782162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:11

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	09 Oct 2020 17:43:02

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:11

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:11

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:11

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:16:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 11:16:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 18:12:51

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:11

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:11

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:11

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '13:21' reason for change: Data Entry Error	Carlton Griffin (b) (4)	12 Oct 2020 14:36:28
User entered '12:21'	(b) (4), (b) (6)	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Temperature (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:11

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Pulse (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:16:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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) (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)	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: 26 Nov 2020 11:16:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 18:22:16

US3782162

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 17:43:09

US3782162

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 17:43:09

US3782162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 18:06:13

US3782162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:11

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:06:13

US3782162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:06:13

US3782162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	09 Oct 2020 18:06:13

US3782162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 18:06:13

US3782162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	09 Oct 2020 18:06:13

US3782162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	09 Oct 2020 18:06:13

US3782162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	09 Oct 2020 18:06:13

US3782162

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 17:47:10

US3782162

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 17:47:10

US3782162

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(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: 26 Nov 2020 11:16:11

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(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: 26 Nov 2020 11:16:11

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 17:47:25

US3782162

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 17:47:30

US3782162

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 17:47:30

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	10 Oct 2020 00:11:08
User entered '97.7'	System	10 Oct 2020 00:11:08

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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 '0'	System	10 Oct 2020 00:11:08

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:16:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	15 Oct 2020 01:27:56
User entered '97.5'	System	15 Oct 2020 01:27:56

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	26 Oct 2020 22:36:06
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).	Carlton Griffin (b) (4)	19 Oct 2020 12:42:29
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).	System	15 Oct 2020 01:27:56
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'	System	15 Oct 2020 01:27:56
User entered '1'	System	15 Oct 2020 01:27:56

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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'	System	15 Oct 2020 01:27:56
User entered '0'	System	15 Oct 2020 01:27:56

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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' User entered '97.8'	System	16 Oct 2020 01:13:54

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	26 Oct 2020 22:36:10
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).	Carlton Griffin (b) (4)	19 Oct 2020 12:42:45
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).	System	16 Oct 2020 01:13:54
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'	System	16 Oct 2020 01:13:54
User entered '1'	System	16 Oct 2020 01:13:54

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	16 Oct 2020 01:13:54
User entered '15 Oct 2020 20:13'	System	16 Oct 2020 01:13:54

US3782162

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:16:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:16:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

FATIGUE

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:16:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 03:13:50

US3782162

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 03:13:50

US3782162

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 03:13:50

US3782162

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 03:13:50

US3782162

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 03:13:55

US3782162

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 03:13:55

US3782162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:29:41

US3782162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:29:41

US3782162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:29:41

US3782162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:29:41

US3782162

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:29:49

US3782162

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 19:29:49

US3782162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:27:13

US3782162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:27:13

US3782162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Oct 2020 20:27:13

US3782162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:16:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:27:13

US3782162

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:27:20

US3782162

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 20:27:20

US3782162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:13

US3782162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '6 Nov 2020'	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:13

US3782162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:13

US3782162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:16:11

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	06 Nov 2020 16:02:13

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '6 Nov 2020'	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:32'	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '74'	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '20'	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '99'	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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 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)	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)	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:16:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Nov 2020 16:02:44

US3782162

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:57

US3782162

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:16:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '6 Nov 2020'	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:02:57

US3782162

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:03:11

US3782162

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '6 Nov 2020'	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:03:11

US3782162

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:50'	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:03:11

US3782162

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	06 Nov 2020 16:03:17

US3782162

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:16:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 16:03:17

US3782162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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: '2020-11-09T10:14:13', 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: 26 Nov 2020 11:16:11

Have you been exposed to someone with 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: '2020-11-09T10:14:17', 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: 26 Nov 2020 11:16:11

[Date and time of submission](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[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: '2020-11-15T17:46:40', 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: 26 Nov 2020 11:16:11

Have you been exposed to someone with 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: '2020-11-15T17:46:45', 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: 26 Nov 2020 11:16:11

[Date and time of submission](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

[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 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: 26 Nov 2020 11:16:11

[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 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: 26 Nov 2020 11:16:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:16:04
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 06:16:04

US3782162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:16:11

[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 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: 26 Nov 2020 11:16:11

[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 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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

Have you been exposed to someone with 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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:16:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:30:21
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	09 Oct 2020 17:29:45
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:11

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:40:24
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute coronary syndrome, LLT: Acute coronary syndrome - version MedDRA\23.0.	Coder Import (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.	(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)	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)	02 Nov 2020 16:13:24
User entered 'acute coronary syndrome' reason for change: Per Query Resolution	Carlton Griffin (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, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Chest pain - cardiac - version MedDRA\23.0.	Coder Import (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)	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: 26 Nov 2020 11:16:11

[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). 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)	25 Oct 2020 16:45:35
	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. Data point term sent to Coder User entered 'chest pain'	Coder Import (b) (4) (b) (4)	09 Oct 2020 17:58:30
	System	09 Oct 2020 17:57:20
	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:41:13
User entered '1'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:11

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
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)	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 '1'	(b) (4), (b) (6)	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 11:16:11

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Narrative](#)

Audit	User	Time (GMT)
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
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

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:11

[Narrative](#)

Audit	User	Time (GMT)
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
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

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:11

[Narrative](#)

Audit	User	Time (GMT)
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
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

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 17:57:04

US3782162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	26 Oct 2020 16:25:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	
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)	26 Oct 2020 15:58:38
Coding entries removed.	(b) (4)	
	Carlton Griffin (b) (4)	26 Oct 2020 15:58:30
User entered 'CARDIAC CHEST PAIN' reason for change: Per Query Resolution	(b) (4)	
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)	25 Oct 2020 16:45:38
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.	(b) (4)	
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	(b) (4)	
	System	19 Oct 2020 12:28:18

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'chest pain'	Carlton Griffin (b) (4) (b) (4)	19 Oct 2020 12:27:53

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:08
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:11
User entered 'No (N)'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:24
User entered 'No (N)'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:35
User entered '14 Oct 2020'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:41
User entered empty.	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 12:27:53

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:45
User entered 'No (N)'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:48
User entered '14 Oct 2020'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:51
User entered empty.	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 12:27:53

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:43:56
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:44:00
User entered 'No (N)'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:44:11
User entered '0'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:44:13
User entered '0'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:44:18
User entered '0'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:44:25
User entered empty.	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:49
User entered empty.	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:44:27
User entered empty.	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:53
User entered empty.	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:54
User entered '0'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:56
User entered '0'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:58
User entered '0'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:50:59
User entered 'Not Related (NOT RELATED)'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:51:01
User entered 'Not Related (NOT RELATED)'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:51:03
User entered 'None (NONE)'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:51:06
User entered '0'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:51:08
User entered '1'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:51:10
User entered '0'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:51:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:51:15
User entered empty.	Carlton Griffin (b) (4)	19 Oct 2020 12:27:53
	(b) (4)	

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	19 Oct 2020 12:27:53

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	19 Oct 2020 12:27:53

US3782162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:16:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 12:27:53

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:16:11

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:52:43
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 19:06:54
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:11

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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)	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)	08 Sep 2020 19:09:26
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:11

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
User entered 'Back Pain'	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: 26 Nov 2020 11:16:11

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Frequency](#)

Audit	User	Time (GMT)
User entered 'four times daily (QID)'	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: 26 Nov 2020 11:16:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Jenna Caserta (b) (4) (b) (4)	08 Sep 2020 19:09:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:16:11

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	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: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	08 Sep 2020 19:12:00
	(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 19:12:00
	(b) (4)	
Data point term sent to Coder	System	08 Sep 2020 19:10:32
User entered 'ASA'	Jenna Caserta (b) (4)	08 Sep 2020 19:10:17
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:18
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:10:17
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:21
User entered 'CAD'	Jenna Caserta (b) (4)	08 Sep 2020 19:10:17
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:25
User entered '325'	Jenna Caserta (b) (4)	08 Sep 2020 19:10:17
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:27
User entered 'mg (mg)'	Jenna Caserta (b) (4)	08 Sep 2020 19:10:17
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:30
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:10:17
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:36
User entered 'once daily (QD)'	Jenna Caserta (b) (4)	08 Sep 2020 19:10:17
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:39
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:10:17
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:45
User entered 'Oral (ORAL)'	Jenna Caserta (b) (4)	08 Sep 2020 19:10:17
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:49
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:10:17
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:51
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:10:17
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:09:53
User entered '1'	Jenna Caserta (b) (4)	08 Sep 2020 19:10:17
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:10:09
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 19:10:17
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:10:11
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:10:17
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:10:20
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:10:17
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[Name of Medication](#)

Audit	User	Time (GMT)
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)	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	System	05 Oct 2020 18:40:37
Coding entries removed.	(b) (4), (b) (6)	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	System	08 Sep 2020 19:11:33
User entered 'Atorvastatin'	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: 26 Nov 2020 11:16:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hyperlipidemia'	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: 26 Nov 2020 11:16:11

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:16:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Route of administration](#)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 11:16:11

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	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: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:16:11

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25/100'	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: 26 Nov 2020 11:16:11

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:16:11

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	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: 26 Nov 2020 11:16:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:16:11

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	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: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:16:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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)	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)	08 Sep 2020 19:13:44

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:16:11

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	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: 26 Nov 2020 11:16:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:16:11

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	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: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:11:07
User entered 'No (N)'	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: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:11:10
User entered 'BPH'	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: 26 Nov 2020 11:16:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:11:17
User entered '5'	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: 26 Nov 2020 11:16:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:11:21
User entered 'mg (mg)'	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: 26 Nov 2020 11:16:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:11:24
User entered empty.	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: 26 Nov 2020 11:16:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:11:27
User entered 'once daily (QD)'	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: 26 Nov 2020 11:16:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:11:29
User entered empty.	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: 26 Nov 2020 11:16:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:11:31
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:16:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:11:34
User entered empty.	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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:11:40
User entered 'un UNK 2015'	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: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:11:41
User entered '0'	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: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:11:45
User entered 'Yes (Y)'	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: 26 Nov 2020 11:16:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:11:48
User entered empty.	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: 26 Nov 2020 11:16:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:11:51
User entered 'No (N)'	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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (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)	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)	08 Sep 2020 19:18:02

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:16:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
User entered 'Back Pain'	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: 26 Nov 2020 11:16:11

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '800'	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: 26 Nov 2020 11:16:11

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:16:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:16:11

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	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: 26 Nov 2020 11:16:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:16:11

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:16:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	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: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '22 Oct 2020' reason for change: New Information	Carlton Griffin (b) (4)	06 Nov 2020 16:15:08
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: 26 Nov 2020 11:16:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:16:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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	System	08 Sep 2020 19:18:44
User entered 'Losartan'	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: 26 Nov 2020 11:16:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:12:39
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:18:39
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:12:45
User entered 'Hypertension'	Jenna Caserta (b) (4)	08 Sep 2020 19:18:39
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:12:52
User entered '50'	Jenna Caserta (b) (4)	08 Sep 2020 19:18:39
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:12:53
User entered 'mg (mg)'	Jenna Caserta (b) (4)	08 Sep 2020 19:18:39
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:11

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:12:57
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:18:39
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:01
User entered 'once daily (QD)'	Jenna Caserta (b) (4)	08 Sep 2020 19:18:39
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:04
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:18:39
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:05
User entered 'Oral (ORAL)'	Jenna Caserta (b) (4)	08 Sep 2020 19:18:39
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:07
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:18:39
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:09
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:18:39
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:12
User entered '1'	Jenna Caserta (b) (4)	08 Sep 2020 19:18:39
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:14
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 19:18:39
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:15
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:18:39
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:17
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:18:39
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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)	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)	08 Sep 2020 19:27:51

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:16:11

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
User entered 'GERD'	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: 26 Nov 2020 11:16:11

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	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: 26 Nov 2020 11:16:11

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:16:11

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	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: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:16:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: BARBITURATES AND DERIVATIVES, PRODUCT: PRIMIDONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (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: 26 Nov 2020 11:16:11

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
User entered 'Tremor'	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: 26 Nov 2020 11:16:11

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 11:16:11

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	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: 26 Nov 2020 11:16:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:16:11

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	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: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	08 Sep 2020 19:31:49
	(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 19:31:49
	(b) (4)	
Data point term sent to Coder	System	08 Sep 2020 19:31:16
User entered 'Flomax'	Jenna Caserta (b) (4)	08 Sep 2020 19:30:28
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:55
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:30:28
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:13:57
User entered 'BPH'	Jenna Caserta (b) (4)	08 Sep 2020 19:30:28
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:14:01
User entered '0.4'	Jenna Caserta (b) (4)	08 Sep 2020 19:30:28
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:14:04
User entered 'mg (mg)'	Jenna Caserta (b) (4)	08 Sep 2020 19:30:28
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:14:08
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:30:28
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:14:06
User entered 'twice daily (BID)'	Jenna Caserta (b) (4)	08 Sep 2020 19:30:28
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:14:10
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:30:28
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:14:12
User entered 'Oral (ORAL)'	Jenna Caserta (b) (4)	08 Sep 2020 19:30:28
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:14:13
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:30:28
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:14:16
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:30:28
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:14:20
User entered '1'	Jenna Caserta (b) (4)	08 Sep 2020 19:30:28
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:14:24
User entered 'Yes (Y)'	Jenna Caserta (b) (4)	08 Sep 2020 19:30:28
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:14:26
User entered empty.	Jenna Caserta (b) (4)	08 Sep 2020 19:30:28
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:14:29
User entered 'No (N)'	Jenna Caserta (b) (4)	08 Sep 2020 19:30:28
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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)	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)	08 Sep 2020 20:06:40
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:11

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
User entered 'general health'	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: 26 Nov 2020 11:16:11

[Dose per administration](#)

Audit	User	Time (GMT)
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) (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)	06 Oct 2020 14:27:48
User entered '5,000' reason for change: Per Query Resolution	Carlton Griffin (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)	08 Sep 2020 20:06:40

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:11

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'IU (IU)' reason for change: Per Query Resolution	Carlton Griffin (b) (4)	06 Oct 2020 14:27:42
User entered 'tablet (TABLET)'	Jenna Caserta (b) (4)	08 Sep 2020 20:06:40

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:16:11

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:16:11

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '8 Sep 2020'	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: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	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)	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)	06 Oct 2020 14:29:04
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:16:11

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
User entered 'general health'	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: 26 Nov 2020 11:16:11

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	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: 26 Nov 2020 11:16:11

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	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: 26 Nov 2020 11:16:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:16:11

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 11:16:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:16:11

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 11:16:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered 'UN UNK 2000'	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: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:16:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:16:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (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)	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: 26 Nov 2020 11:16:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(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: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
User entered 'post-vaccination symptom prophylaxis'	(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: 26 Nov 2020 11:16:11

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	(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: 26 Nov 2020 11:16:11

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(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: 26 Nov 2020 11:16:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 11:16:11

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(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: 26 Nov 2020 11:16:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 11:16:11

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(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: 26 Nov 2020 11:16:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(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: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(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: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 11:16:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(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: 26 Nov 2020 11:16:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 11:16:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	19 Oct 2020 12:32:43

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:11

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:16:29
User entered 'No (N)'	Carlton Griffin (b) (4)	19 Oct 2020 12:32:43
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:16:31
User entered 'chest pain'	Carlton Griffin (b) (4)	19 Oct 2020 12:32:43
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:16:36
User entered '0.4'	Carlton Griffin (b) (4)	19 Oct 2020 12:32:43
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:16:37
User entered 'mg (mg)'	Carlton Griffin (b) (4)	19 Oct 2020 12:32:43
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:16:40
User entered empty.	Carlton Griffin (b) (4)	19 Oct 2020 12:32:43
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:16:42
User entered 'once (ONCE)'	Carlton Griffin (b) (4)	19 Oct 2020 12:32:43
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:16:43
User entered empty.	Carlton Griffin (b) (4)	19 Oct 2020 12:32:43
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:16:45
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4)	19 Oct 2020 12:32:43
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:17:12
User entered empty.	Carlton Griffin (b) (4)	19 Oct 2020 12:32:43
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:17:16
User entered '14 Oct 2020'	Carlton Griffin (b) (4)	19 Oct 2020 12:32:43
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:17:20
User entered '0'	Carlton Griffin (b) (4)	19 Oct 2020 12:32:43
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:17:23
User entered 'No (N)'	Carlton Griffin (b) (4)	19 Oct 2020 12:32:43
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:17:26
User entered '14 Oct 2020'	Carlton Griffin (b) (4)	19 Oct 2020 12:32:43
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:17:28
User entered 'No (N)'	Carlton Griffin (b) (4)	19 Oct 2020 12:32:43
	(b) (4)	

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:16:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	30 Oct 2020 20:29:00

US3782162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:16:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(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: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
User entered 'influenza prophylaxis'	(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: 26 Nov 2020 11:16:11

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5'	(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: 26 Nov 2020 11:16:11

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	(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: 26 Nov 2020 11:16:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 11:16:11

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(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: 26 Nov 2020 11:16:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 11:16:11

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	(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: 26 Nov 2020 11:16:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
User entered '26 Oct 2020' reason for change: Data Entry Error	(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: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(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: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 11:16:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Oct 2020' reason for change: Data Entry Error	(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: 26 Nov 2020 11:16:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 11:16:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4)	31 Oct 2020 01:06:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 01:06:13
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: 26 Nov 2020 11:16:11

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[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: 26 Nov 2020 11:16:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Oct 2020 20:31:46

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:16:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:46
User entered '22 Oct 2020'	Carlton Griffin (b) (4)	23 Oct 2020 19:30:36
	(b) (4)	

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:16:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:51
User entered 'colonoscopy'	Carlton Griffin (b) (4)	23 Oct 2020 19:30:36
	(b) (4)	

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:16:11

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:53
User entered 'Other (OTHER)'	Carlton Griffin (b) (4)	23 Oct 2020 19:30:36
	(b) (4)	

US3782162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:16:11

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:59:55
User entered 'routine'	Carlton Griffin (b) (4)	23 Oct 2020 19:30:36
	(b) (4)	

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [State](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [State](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

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)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 18:57:45
User entered '1'	(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: 26 Nov 2020 11:16:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [State](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

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)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 18:15:54
User entered '1'	(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: 26 Nov 2020 11:16:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [State](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

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)	10 Nov 2020 17:35:55
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 14:58:24
User entered '1'	(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: 26 Nov 2020 11:16:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Site Address:](#) State

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

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)	10 Nov 2020 17:35:55
User entered '1'	(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: 26 Nov 2020 11:16:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [State](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 12:59:56

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 11:16:11

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

Site Address: [State](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:16:11

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 12:59:56

US3782162

Folder: SAE USA-US125-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:16:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:16:11

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)	10 Nov 2020 17:36:07
User entered '1'	(b) (4), (b) (6)	27 Oct 2020 12:59:56