

US3742477 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:15:06

All time stamps listed in this document are displayed in GMT

US3742477

Form: Participant Creation

Generated On: 26 Nov 2020 11:15:06

[Participant ID](#)

US3742477

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

US3742477

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3742477

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:06

Date of Birth (MMM yyyy)	(b) (6) 1971
Age	49
Age Units	YEARS
Age (Derived)	49
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
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	True

US3742477

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:06

Date of Informed Consent (<i>dd MMM yyyy</i>)	28 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

US3742477

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:15:06

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3742477

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:15:06

Were any significant conditions reported?

Yes ☒

No ☐

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:06

Condition	ASTHMA
Start date (dd MMM yyyy)	UN APR 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)	APR 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:06

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN DEC 2016
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)	DEC 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3742477

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:06

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	6 MAR 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	6 MAR 1998
Stop date completely unknown	False
Start Month and Year (derived)	MAR 1998
Start Year (derived)	1998
Stop Month and Year (derived)	MAR 1998
Stop Year (derived)	1998

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:06

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

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:06

Condition	LEFT KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN DEC 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN DEC 2016
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2016
Start Year (derived)	2016
Stop Month and Year (derived)	DEC 2016
Stop Year (derived)	2016

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:06

Condition	CONSTIPATION
Start date (dd MMM yyyy)	UN AUG 2020
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)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	28 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:16 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 13:16
Height (<i>xxx.x</i>)	61.0 in
Weight (<i>xxx.x</i>)	230.1 lb
BMI (<i>xxx.x</i>)	43.56792 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	098.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	064 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	076 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3742477

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3742477

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:06

Date of assessment (*dd MMM yyyy*) 28 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) 6 MAR 1998

Date of surgery unknown False

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

Date of last menstruation unknown False

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

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

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

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)	False
Other	True
Specify	GROVERY STORE SHOPPING

US3742477

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	01 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3742477

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:06

What was the date of randomization? (dd MMM yyyy) 01 OCT 2020

What was the participant's randomization number? 146701

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 ☒

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:06

Height	61.5 in
Weight	231.2 lb

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

Height	61.5 in
Weight	231.2 lb
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	01 OCT 2020
Time of assessment (00:00-23:59)	12:13 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 12:13
Temperature (xxx.x)	98.7 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

Height	61.5 in
Weight	231.2 lb
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	01 OCT 2020
Time of assessment (00:00-23:59)	13:36 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 13:36
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	57 mmHg
Diastolic Blood Pressure units	MMHG

US3742477

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

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

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

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)	1 OCT 2020
What was the treatment time? (00:00-23:59)	13:04 (24 HR)
Treatment Date and Time (derived)	1 OCT 2020 13:04
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 11:15:06

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

01 OCT 2020

Collection time (*00:00-23:59*)

12:29 (24 HR)

Collection date and time (derived)

01 OCT 2020 12:29

US3742477

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:06

Collection date (<i>dd MMM yyyy</i>)			01 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:34	01 OCT 2020 12:34
Nasopharyngeal Swab 2	No		

US3742477

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp 01 OCT 2020 13:41

PC Open Date & Time 01 OCT 2020 13:24

PC Close Date & Time 01 OCT 2020 15:54

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

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

97.0 °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 01 OCT 2020 18:42

PC Open Date & Time 01 OCT 2020 16:49

PC Close Date & Time 02 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp 02 OCT 2020 18:26

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 15:49

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:06

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

97.5 °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

04 OCT 2020 19:04

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 19:36

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	True
PC Time Stamp	06 OCT 2020 22:07
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:06

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	97.9 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

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

PC Time Stamp	07 OCT 2020 16:10
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 11:15:06

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

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

08 OCT 2020 19:53

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

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

01 OCT 2020 13:40

PC Open Date & Time

01 OCT 2020 13:24

PC Close Date & Time

01 OCT 2020 15:54

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

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

01 OCT 2020 18:43

PC Open Date & Time

01 OCT 2020 16:49

PC Close Date & Time

02 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:06

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

02 OCT 2020 18:27

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:06

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

03 OCT 2020 15:50

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:06

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

04 OCT 2020 19:05

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:06

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

05 OCT 2020 19:36

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:06

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

06 OCT 2020 22:08

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:06

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

07 OCT 2020 16:11

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 13:42
PC Open Date & Time	01 OCT 2020 13:24
PC Close Date & Time	01 OCT 2020 15:54

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 18:43
PC Open Date & Time	01 OCT 2020 16:49
PC Close Date & Time	02 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:06

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 ☒

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:06

Yes ☐	
PC Time stamp	02 OCT 2020 18:28
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:06

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 ☒

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:06

Yes ☐	
PC Time stamp	03 OCT 2020 15:51
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:06

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 ☒

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:06

Yes ☐	
PC Time stamp	04 OCT 2020 19:06
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:06

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 ☒

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:06

Yes ☐	
PC Time stamp	05 OCT 2020 19:37
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:06

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 ☒

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:06

Yes ☐	
PC Time stamp	06 OCT 2020 22:08
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:06

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 ☒

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:06

Yes ☐	
PC Time stamp	07 OCT 2020 16:11
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp 08 OCT 2020 19:53

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 09 OCT 2020 19:30

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 10 OCT 2020 19:59

PC Open Date & Time 10 OCT 2020 12:00

PC Close Date & Time 11 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp	08 OCT 2020 19:54

PC Open Date & Time	08 OCT 2020 12:00

PC Close Date & Time	09 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp	09 OCT 2020 19:30

PC Open Date & Time	09 OCT 2020 12:00

PC Close Date & Time	10 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	08 OCT 2020 19:54
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	09 OCT 2020 19:30
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3742477

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742477

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742477

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

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

US3742477

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

Was this visit performed?	Yes ☐
	No ☒

Visit date (dd MMM yyyy)	

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

Folder OID	VISIT2

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3742477

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:06

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.

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

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? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3742477

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:06

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:06

Collection date (*dd MMM yyyy*)

Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3742477

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

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

PARTICIPANT IN
CONVALESCENT PERIOD

If Contact Not Made, please provide Comments

US3742477

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

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

US3742477

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

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

US3742477

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	23 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	13:47 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 13:47
Temperature (<i>xxx.x</i>)	098.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	78 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	070 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 NOV 2020

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

US3742477

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:06

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	23 NOV 2020
Collection time (<i>00:00-23:59</i>)	14:20 (24 HR)
Collection date and time (derived)	23 NOV 2020 14:20

US3742477

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

16 DEC 2020 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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13 JAN 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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16 JAN 2021 00:01

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20 JAN 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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23 JAN 2021 00:01

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27 JAN 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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03 FEB 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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17 MAR 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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27 MAR 2021 00:01

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31 MAR 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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19 FEB 2022 00:01

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23 FEB 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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26 FEB 2022 00:01

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02 MAR 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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05 MAR 2022 00:01

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09 MAR 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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16 MAR 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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23 MAR 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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30 MAR 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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08 JUN 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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15 JUN 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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22 JUN 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

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29 JUN 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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06 JUL 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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13 JUL 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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20 JUL 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

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27 JUL 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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13 AUG 2022 00:01

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17 AUG 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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20 AUG 2022 00:01

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24 AUG 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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27 AUG 2022 00:01

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31 AUG 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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03 SEP 2022 00:01

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07 SEP 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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10 SEP 2022 00:01

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14 SEP 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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21 SEP 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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15 OCT 2022 00:01

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19 OCT 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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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22 OCT 2022 00:01

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26 OCT 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

30 NOV 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

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

[Patient Cloud Close Date & Time](#)

07 DEC 2022 23:59

US3742477

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

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

US3742477

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:06

Date of Contact	19 OCT 2020
Time of Contact	10:00
Date and Time of Contact (derived)	19 OCT 2020 10:00
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 ☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	14 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	309 of 2212	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	15 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	313 of 2212	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☒
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	317 of 2212	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	17 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	321 of 2212	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	18 OCT 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	325 of 2212	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	19 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	329 of 2212	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	20 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	333 of 2212	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	21 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	99.3 F	
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	337 of 2212	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	22 OCT 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	341 of 2212	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☒
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	23 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	100.8 F	
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	345 of 2212	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☒
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	24 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	349 of 2212	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☒
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	25 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	353 of 2212	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:06

Date of Visit	19 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Date of Test	19 OCT 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	1

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☐

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☐

Start Date _____

If Yes to either Did subject require any of the following:

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

Ventilator Support:

High-Flow Oxygen? Yes ☐ No ☒

Start Date _____

End Date _____

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date _____

End Date _____

Mechanical Ventilation? Yes ☐ No ☒

Start Date _____

End Date _____

ECMO? Yes ☐ No ☒

Start Date _____

End Date _____

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐ No ☒

Start Date _____

End Date _____

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date _____

End Date _____

Acute Renal Dysfunction? Yes ☐ No ☒

Start Date _____

Hepatic Dysfunction? Yes ☐ No ☒

Start Date _____

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:15:06

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 11:15:06

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	21 OCT 2020
Day 5	Yes	23 OCT 2020
Day 7	Yes	26 OCT 2020
Day 9	Yes	27 OCT 2020
Day 14	Yes	02 NOV 2020
Day 21	Yes	09 NOV 2020
Day 28	No	

US3742477

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	19 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:28 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 12:28
Height (<i>xxx.x</i>)	155 cm
Weight (<i>xxx.x</i>)	226.8 lb
Temperature (<i>xxx.x</i>)	98.6 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	78 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3742477

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3742477

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:15:06

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

19 OCT 2020

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD28

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	23 NOV 2020
Time of assessment (00:00-23:59)	13:47 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 13:47
Height (xxx.x)	62.0 in
Weight (xxx.x)	225.7 lb
Temperature (xxx.x)	098.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	081 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 NOV 2020

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

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:15:06

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 NOV 2020

US3742477

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:15:06

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

AEID	
Adverse event	RHINORRHEA
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)	07 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)	07 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	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

371 of 2212

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

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

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

AEID	
Adverse event	NASAL CONGESTION
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)	7 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)	8 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	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

373 of 2212

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

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

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

AEID	
Adverse event	BILATERAL SHOULDER 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)	13 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)	26 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	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

375 of 2212

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

AEID	
Adverse event	LEFT ELBOW 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)	13 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)	26 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	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

377 of 2212

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

AEID	USA-US127-2020-MRNA-1273-P30 1000006
Adverse event	SYMPTOMATIC COVID-19
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)	31 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)	379 of 2212

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

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

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

AEID	
Adverse event	BILATERAL FOREARM 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)	16 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

381 of 2212

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☒ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:15:06

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

Yes ☒

No ☐

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

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

Name of Medication	K-21 MINERAL SUPPLEMENT
Prophylaxis	Yes ☒ No ☐
Indication	SUPPLEMENT
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	TBSP
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 ☐

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

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 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)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

Name of Medication	DIETARY PROTEIN SUPPLEMENT
Prophylaxis	Yes ☒ No ☐
Indication	SUPPLEMENT
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	PACKET
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 ☐

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAY 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	☒

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

Name of Medication	HERBAL LAXATIVE TEA
Prophylaxis	Yes ☐ No ☒
Indication	CONSTIPATION
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	PACKET
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 ☐

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

	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 AUG 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

Name of Medication	QVAR INHALER
Prophylaxis	Yes ☐ No ☒
Indication	ASTHMA
Dose per administration	80
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

	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 APR 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

Name of Medication	DICLOFENAC
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOARTHRITIS, KNEE PAIN, JOINT PAIN
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 ☐

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

	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)		
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	☐

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	MUSCLE ACHES
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

	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)		05 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		07 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	☐

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

Name of Medication ACETAMINOPHEN+DEXTROME
THORPHAN+PHENYLEPHRINE

Prophylaxis Yes ☐
No ☒

Indication RHINORRHEA AND NASAL
CONGESTION

Dose per administration 650/20/10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

	Intraocular	☐
	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)	07 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 07 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	☐

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

Name of Medication	ACETAMENOPHEN
Prophylaxis	Yes ☐ No ☒
Indication	SYMPTOMATIC COVID-19
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

	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)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		30 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 ☐

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	SYMPTOMATIC COVID-19
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 ☐

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

	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)		23 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		25 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 ☐

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ☒
Indication	THROMBOSIS
Dose per administration	81
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	01 NOV 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 ☒	

US3742477

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:15:06

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3742477

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:06

Date of dosing discontinuation (dd MMM yyyy)

23 OCT 2020

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☒

Other ☐

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

US3742477

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:15:06

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 ☐

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

SAEID	USA-US127-2020-MRNA-1273-P301000006
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:15:06

SAEID	USA-US127-2020-MRNA-1273-P301000006
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/OCT/2020 17:00
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:15:06

SAEID	USA-US127-2020-MRNA-1273-P301000006
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/NOV/2020 20:17
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

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:15:06

SAEID	USA-US127-2020-MRNA-1273-P301000006
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/NOV/2020 20:27
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

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:15:06

SAEID	USA-US127-2020-MRNA-1273-P301000006
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	10/NOV/2020 09:16
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

Audit

US3742477 (Prod: University of Maryland School of Medicine)

US3742477

Form: Participant Creation

Generated On: 26 Nov 2020 11:15:06

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3742477'	RWS_ENDPOINT ENDPOINT (b) (4) 	28 Sep 2020 16:37:52

US3742477

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 13:53:25

US3742477

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '28 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Sep 2020 16:37:53

US3742477

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	29 Sep 2020 13:53:25

US3742477

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	29 Sep 2020 13:53:25

US3742477

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:06

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1971'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Sep 2020 16:42:42

US3742477

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:06

[Age](#)

Audit	User	Time (GMT)
User entered '49'	(b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:06

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:06

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '49'	System	29 Sep 2020 13:54:54

US3742477

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:06

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:06

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:06

[White](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:06

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:06

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:06

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:06

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:06

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:06

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:06

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:06

[Not reported](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 13:54:54

US3742477

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	29 Sep 2020 13:54:54

US3742477

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '2020'	System	29 Sep 2020 13:54:54

US3742477

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:06

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	29 Sep 2020 13:54:54

US3742477

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 13:54:54

US3742477

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 13:54:54

US3742477

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:06

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 13:54:54

US3742477

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:06

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 13:54:54

US3742477

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:06

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Sep 2020 16:37:53

US3742477

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:06

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 13:55:30

US3742477

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 13:55:30

US3742477

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:15:06

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:11:52

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:14:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:14:03
Data point term sent to Coder	System	29 Sep 2020 14:12:57
User entered 'ASTHMA'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 14:12:08

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'UN Apr 2017'	(b) (4), (b) (6)	29 Sep 2020 14:12:08

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:12:08

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:12:08

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:12:08

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:12:08

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Apr 2017'	System	29 Sep 2020 14:12:08

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '2017'	System	29 Sep 2020 14:12:08

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 14:12:08

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 14:12:08

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:14:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:14:04
Data point term sent to Coder	System	29 Sep 2020 14:12:58
User entered 'OSTEOARTHRITIS'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 14:12:30

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'UN Dec 2016'	(b) (4), (b) (6)	29 Sep 2020 14:12:30

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:12:30

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:12:30

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:12:30

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:12:30

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Dec 2016'	System	29 Sep 2020 14:12:30

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '2016'	System	29 Sep 2020 14:12:30

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 14:12:30

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 14:12:30

US3742477

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 14:14:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 14:14:03
Data point term sent to Coder	System	29 Sep 2020 14:13:00
User entered 'TUBAL LIGATION'	(b) (4), (b) (6)	29 Sep 2020 14:12:53

US3742477

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '6 Mar 1998'	(b) (4), (b) (6)	29 Sep 2020 14:12:53

US3742477

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:12:53

US3742477

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	29 Sep 2020 14:14:19
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	29 Sep 2020 14:12:53
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:12:53

US3742477

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '6 Mar 1998' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 14:14:19
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:12:53

US3742477

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:12:53

US3742477

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Mar 1998'	System	29 Sep 2020 14:12:53

US3742477

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '1998'	System	29 Sep 2020 14:12:53

US3742477

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Mar 1998'	System	29 Sep 2020 14:14:19
User entered empty.	System	29 Sep 2020 14:12:53

US3742477

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '1998'	System	29 Sep 2020 14:14:19
User entered empty.	System	29 Sep 2020 14:12:53

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Cyst removal, LLT: Cyst removal - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:37:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:37:43
Data point term sent to Coder	System	29 Sep 2020 14:14:03
User entered 'CYST REMOVAL(LEFT HAND)'	(b) (4), (b) (6) (b) (4)	29 Sep 2020 14:13:26

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'UN UNK 1995'	(b) (4), (b) (6)	29 Sep 2020 14:13:26

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:13:26

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:13:26

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'UN UNK 1995'	(b) (4), (b) (6)	29 Sep 2020 14:13:26

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:13:26

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	29 Sep 2020 14:13:26

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '1995'	System	29 Sep 2020 14:13:26

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	29 Sep 2020 14:13:26

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '1995'	System	29 Sep 2020 14:13:26

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:06

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:14:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:14:50
Data point term sent to Coder	System	29 Sep 2020 14:14:04
User entered 'LEFT KNEE REPLACEMENT'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 14:13:56

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'UN Dec 2016'	(b) (4), (b) (6)	29 Sep 2020 14:13:56

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:13:56

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:13:56

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'UN Dec 2016'	(b) (4), (b) (6)	29 Sep 2020 14:13:56

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:13:56

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Dec 2016'	System	29 Sep 2020 14:13:56

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '2016'	System	29 Sep 2020 14:13:56

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Dec 2016'	System	29 Sep 2020 14:13:56

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '2016'	System	29 Sep 2020 14:13:56

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:06

[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)	31 Oct 2020 20:01:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 20:01:22
Data point term sent to Coder	System	31 Oct 2020 20:00:33
User entered 'CONSTIPATION'	(b) (4), (b) (6)	31 Oct 2020 19:59:53

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'UN Aug 2020'	(b) (4), (b) (6)	31 Oct 2020 19:59:53

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Oct 2020 19:59:53

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Oct 2020 19:59:53

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	31 Oct 2020 19:59:53

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	31 Oct 2020 19:59:53

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	31 Oct 2020 19:59:53

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '2020'	System	31 Oct 2020 19:59:53

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 19:59:53

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	System	31 Oct 2020 19:59:53

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '13:16'	(b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '28 Sep 2020 13:16'	System	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '61.0' in	(b) (4), (b) (6)	29 Sep 2020 14:10:48
DataPoint set to visible.	System	29 Sep 2020 13:55:30

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '230.1' lb	(b) (4), (b) (6)	29 Sep 2020 14:10:48
DataPoint set to visible.	System	29 Sep 2020 13:55:30

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '43.56792'	System	29 Sep 2020 14:10:48
DataPoint set to visible.	System	29 Sep 2020 13:55:30

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	29 Sep 2020 14:10:48
DataPoint set to visible.	System	29 Sep 2020 13:55:30

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '098.1' F	(b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '064'	(b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '119'	(b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '076'	(b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:11:18

US3742477

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:11:18

US3742477

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '28 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:08:40

US3742477

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:08:40

US3742477

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4), (b) (6)	29 Sep 2020 14:08:40

US3742477

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:06

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:08:40

US3742477

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:06

[If Surgically sterile, date of surgery \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '6 Mar 1998'	(b) (4), (b) (6)	29 Sep 2020 14:08:40

US3742477

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:06

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:08:40

US3742477

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:08:40

US3742477

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:06

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:08:40

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

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)'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

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)'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

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 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

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)'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

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)'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

Other

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

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'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

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'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

Other

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:06

[Specify](#)

Audit	User	Time (GMT)
User entered 'GROVERY STORE SHOPPING'	(b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 17:34:02

US3742477

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '01 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 14:35:19
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 17:34:02

US3742477

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Oct 2020 17:34:02

US3742477

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	01 Oct 2020 17:34:02

US3742477

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '01 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	01 Oct 2020 16:42:46

US3742477

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '146701'	RWS_ENDPOINT ENDPOINT (b) (4) 	01 Oct 2020 16:42:46

US3742477

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Oct 2020 16:42:46

US3742477

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:06

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)'	(b) (4), (b) (6)	01 Oct 2020 17:55:07

US3742477

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 17:55:07

US3742477

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 17:55:07

US3742477

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:06

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 17:55:07

US3742477

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:06

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 17:55:07

US3742477

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 17:55:07
DataPoint set to visible.	System	29 Sep 2020 13:54:54

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:06

Height

Audit	User	Time (GMT)
User entered '61.5' in	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:06

Weight

Audit	User	Time (GMT)
User entered '231.2' lb	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:06

Height

Audit	User	Time (GMT)
User entered '61.5' in	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:06

Weight

Audit	User	Time (GMT)
User entered '231.2' lb	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '12:13'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:13'	System	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '86'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '113'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '73'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:06

Height

Audit	User	Time (GMT)
User entered '61.5' in	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:06

Weight

Audit	User	Time (GMT)
User entered '231.2' lb	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '13:36'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '01 Oct 2020 13:36'	System	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '73'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '12'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '106'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

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)	02 Oct 2020 19:05:13
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 'Not clinically significant' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 18:29:06
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).		01 Oct 2020 17:57:03
User entered '57'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 17:58:05

US3742477

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:06

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 17:58:05

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 17:34:50

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 17:34:50

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

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)	01 Oct 2020 17:34:50

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 17:34:50

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 17:34:50

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '13:04'	(b) (4), (b) (6)	01 Oct 2020 17:34:50

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '1 Oct 2020 13:04'	System	01 Oct 2020 17:34:50

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	01 Oct 2020 17:34:50

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	01 Oct 2020 17:34:50

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 17:34:50

US3742477

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 17:58:24

US3742477

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '01 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 17:58:24

US3742477

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:29'	(b) (4), (b) (6)	01 Oct 2020 17:58:24

US3742477

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:29'	System	01 Oct 2020 17:58:24

US3742477

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '01 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 17:58:44

US3742477

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:06

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	01 Oct 2020 17:58:44

US3742477

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 17:58:44

US3742477

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:06

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '12:34'	(b) (4), (b) (6)	01 Oct 2020 17:58:44

US3742477

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:34'	System	01 Oct 2020 17:58:44

US3742477

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:06

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	01 Oct 2020 17:58:44

US3742477

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 17:58:44

US3742477

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:06

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 17:58:44

US3742477

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 17:58:44

US3742477

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 17:58:48

US3742477

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 17:58:48

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:07', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '58eb2f55-708c-49ee-9a46-a6d04a0ebef6' User entered 'Yes (Y)'	System	01 Oct 2020 17:41:35
	System	01 Oct 2020 17:41:35

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:17', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '58eb2f55-708c-49ee-9a46-a6d04a0ebef6'	System	01 Oct 2020 17:41:35
User entered '98.1'	System	01 Oct 2020 17:41:35

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:22', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '58eb2f55-708c-49ee-9a46-a6d04a0ebef6'	System	01 Oct 2020 17:41:35
User entered 'No (N)'	System	01 Oct 2020 17:41:35

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:29', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '58eb2f55-708c-49ee-9a46-a6d04a0ebef6'	System	01 Oct 2020 17:41:35
User entered '01 Oct 2020 13:41'	System	01 Oct 2020 17:41:35

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 13:24'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 15:54'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:42:23', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '00b33e06-80d2-49aa-953f-38b01ad2ca1f' User entered 'Yes (Y)'	System	01 Oct 2020 22:42:52
	System	01 Oct 2020 22:42:52

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:42:35', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '00b33e06-80d2-49aa-953f-38b01ad2ca1f' User entered '97.0'	System	01 Oct 2020 22:42:52
	System	01 Oct 2020 22:42:52

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:42:39', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '00b33e06-80d2-49aa-953f-38b01ad2ca1f' User entered 'No (N)'	System	01 Oct 2020 22:42:52

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:42:49', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '00b33e06-80d2-49aa-953f-38b01ad2ca1f' User entered '01 Oct 2020 18:42'	System	01 Oct 2020 22:42:52
	System	01 Oct 2020 22:42:52

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 16:49'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 2'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:26:06', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'bb156bc8-ba47-4d8d-9aca-1b0a80d0daa0'	System	02 Oct 2020 22:26:38
User entered 'Yes (Y)'	System	02 Oct 2020 22:26:38

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:26:25', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'bb156bc8-ba47-4d8d-9aca-1b0a80d0daa0'	System	02 Oct 2020 22:26:38
User entered '98.2'	System	02 Oct 2020 22:26:38

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:26:29', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'bb156bc8-ba47-4d8d-9aca-1b0a80d0daa0'	System	02 Oct 2020 22:26:38
User entered 'No (N)'	System	02 Oct 2020 22:26:38

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:26:35', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'bb156bc8-ba47-4d8d-9aca-1b0a80d0daa0'	System	02 Oct 2020 22:26:38
User entered '02 Oct 2020 18:26'	System	02 Oct 2020 22:26:38

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 3'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:49:32', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '344761c7-38fa-4196-a18e-009ef1df1bd2'	System	03 Oct 2020 19:49:48
User entered 'Yes (Y)'	System	03 Oct 2020 19:49:48

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:49:39', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '344761c7-38fa-4196-a18e-009ef1df1bd2'	System	03 Oct 2020 19:49:48
User entered '96.8'	System	03 Oct 2020 19:49:48

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:49:43', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '344761c7-38fa-4196-a18e-009ef1df1bd2'	System	03 Oct 2020 19:49:48
User entered 'No (N)'	System	03 Oct 2020 19:49:48

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:49:46', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '344761c7-38fa-4196-a18e-009ef1df1bd2'	System	03 Oct 2020 19:49:48
User entered '03 Oct 2020 15:49'	System	03 Oct 2020 19:49:48

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 4'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:04:37', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0326af3a-c017-4061-8f27-c68853eddb20'	System	04 Oct 2020 23:05:00
User entered 'Yes (Y)'	System	04 Oct 2020 23:05:00

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:04:43', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0326af3a-c017-4061-8f27-c68853eddb20'	System	04 Oct 2020 23:05:00
User entered '97.5'	System	04 Oct 2020 23:05:00

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:04:47', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0326af3a-c017-4061-8f27-c68853eddb20'	System	04 Oct 2020 23:05:00
User entered 'No (N)'	System	04 Oct 2020 23:05:00

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:04:50', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0326af3a-c017-4061-8f27-c68853eddb20' User entered '04 Oct 2020 19:04'	System	04 Oct 2020 23:05:00
	System	04 Oct 2020 23:05:00

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 5'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:12', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '2251ed89-6096-49ca-8d63-347d650012b5'	System	05 Oct 2020 23:36:28
User entered 'Yes (Y)'	System	05 Oct 2020 23:36:28

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:18', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '2251ed89-6096-49ca-8d63-347d650012b5'	System	05 Oct 2020 23:36:28
User entered '97.8'	System	05 Oct 2020 23:36:28

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:21', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '2251ed89-6096-49ca-8d63-347d650012b5'	System	05 Oct 2020 23:36:28
User entered 'No (N)'	System	05 Oct 2020 23:36:28

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:24', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '2251ed89-6096-49ca-8d63-347d650012b5'	System	05 Oct 2020 23:36:28
User entered '05 Oct 2020 19:36'	System	05 Oct 2020 23:36:28

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 6'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:06:45', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92dcb4f7-b6fe-4432-962b-488c770b40bf'	System	07 Oct 2020 02:07:44
User entered 'Yes (Y)'	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:06:52', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92dcb4f7-b6fe-4432-962b-488c770b40bf' User entered '97.2'	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:07:08', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92dcb4f7-b6fe-4432-962b-488c770b40bf'	System	07 Oct 2020 02:07:44
User entered 'Yes (Y)'	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:06

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). 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 'ADDED' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 09:19:59
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:07:36', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92dcb4f7-b6fe-4432-962b-488c770b40bf' User entered '1'	Kaitlin Mason (b) (4)	24 Oct 2020 16:58:55
	System	07 Oct 2020 02:07:44
	System	07 Oct 2020 02:07:44
	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:06

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 'ADDED' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 09:20:02
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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:07:36', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92dcb4f7-b6fe-4432-962b-488c770b40bf' User entered '1'	Kaitlin Mason (b) (4)	24 Oct 2020 16:58:59
	System	07 Oct 2020 02:07:44
	System	07 Oct 2020 02:07:44
	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:07:43', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92dcb4f7-b6fe-4432-962b-488c770b40bf'	System	07 Oct 2020 02:07:44
User entered '06 Oct 2020 22:07'	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 7'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:10:27', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9d81c8f3-96c3-420b-ae8d-b6de2f1cf045'	System	07 Oct 2020 20:10:54
User entered 'Yes (Y)'	System	07 Oct 2020 20:10:54

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:10:32', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9d81c8f3-96c3-420b-ae8d-b6de2f1cf045'	System	07 Oct 2020 20:10:54
User entered '97.9'	System	07 Oct 2020 20:10:54

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:10:39', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9d81c8f3-96c3-420b-ae8d-b6de2f1cf045'	System	07 Oct 2020 20:10:54
User entered 'Yes (Y)'	System	07 Oct 2020 20:10:54

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:06

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). 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 'ADDED' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 09:21:07
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:10:50', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9d81c8f3-96c3-420b-ae8d-b6de2f1cf045'	Kaitlin Mason (b) (4)	24 Oct 2020 16:59:17
User entered '1'	System	07 Oct 2020 20:10:54
	System	07 Oct 2020 20:10:54
	System	07 Oct 2020 20:10:54

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:06

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:10:50', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9d81c8f3-96c3-420b-ae8d-b6de2f1cf045'	System	07 Oct 2020 20:10:54
User entered '0'	System	07 Oct 2020 20:10:54

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:10:52', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9d81c8f3-96c3-420b-ae8d-b6de2f1cf045'	System	07 Oct 2020 20:10:54
User entered '07 Oct 2020 16:10'	System	07 Oct 2020 20:10:54

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 02:07:44
User entered 'Day 8'	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 11:15:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:52:50', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8f8d9869-4fb9-4411-96a7-e2f67ee94003'	System	08 Oct 2020 23:53:12
User entered 'Yes (Y)'	System	08 Oct 2020 23:53:12

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 11:15:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:52:58', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8f8d9869-4fb9-4411-96a7-e2f67ee94003'	System	08 Oct 2020 23:53:12
User entered '98.0'	System	08 Oct 2020 23:53:12

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:53:05', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8f8d9869-4fb9-4411-96a7-e2f67ee94003'	System	08 Oct 2020 23:53:12
User entered 'No (N)'	System	08 Oct 2020 23:53:12

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:53:09', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8f8d9869-4fb9-4411-96a7-e2f67ee94003'	System	08 Oct 2020 23:53:12
User entered '08 Oct 2020 19:53'	System	08 Oct 2020 23:53:12

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:37:54', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '5906d7c8-3876-444f-be43-38ba2b490c8c'	System	01 Oct 2020 17:40:24
User entered 'None (1)'	System	01 Oct 2020 17:40:24

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:38:20', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '5906d7c8-3876-444f-be43-38ba2b490c8c'	System	01 Oct 2020 17:40:24
User entered 'No (N)'	System	01 Oct 2020 17:40:24

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:38:27', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '5906d7c8-3876-444f-be43-38ba2b490c8c'	System	01 Oct 2020 17:40:24
User entered 'No (N)'	System	01 Oct 2020 17:40:24

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:39:58', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '5906d7c8-3876-444f-be43-38ba2b490c8c'	System	01 Oct 2020 17:40:24
User entered 'None (1)'	System	01 Oct 2020 17:40:24

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:40:19', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '5906d7c8-3876-444f-be43-38ba2b490c8c' User entered '01 Oct 2020 13:40'	System	01 Oct 2020 17:40:24
	System	01 Oct 2020 17:40:24

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 13:24'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 15:54'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:42:57', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7ce202ad-a9e0-49ec-8fbe-bdb85319a845'	System	01 Oct 2020 22:43:24
User entered 'None (1)'	System	01 Oct 2020 22:43:24

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7ce202ad-a9e0-49ec-8fbe-bdb85319a845'	System	01 Oct 2020 22:43:24
User entered 'No (N)'	System	01 Oct 2020 22:43:24

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:03', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7ce202ad-a9e0-49ec-8fbe-bdb85319a845'	System	01 Oct 2020 22:43:24
User entered 'No (N)'	System	01 Oct 2020 22:43:24

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:13', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7ce202ad-a9e0-49ec-8fbe-bdb85319a845'	System	01 Oct 2020 22:43:24
User entered 'None (1)'	System	01 Oct 2020 22:43:24

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:19', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7ce202ad-a9e0-49ec-8fbe-bdb85319a845'	System	01 Oct 2020 22:43:24
User entered '01 Oct 2020 18:43'	System	01 Oct 2020 22:43:24

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 16:49'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 2'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:06

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:26:53', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '176f62ba-c382-4e93-a759-cf3c80715de2'	System	02 Oct 2020 22:27:57
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 22:27:57

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:27:28', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '176f62ba-c382-4e93-a759-cf3c80715de2'	System	02 Oct 2020 22:27:57
User entered 'No (N)'	System	02 Oct 2020 22:27:57

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:27:40', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '176f62ba-c382-4e93-a759-cf3c80715de2'	System	02 Oct 2020 22:27:57
User entered 'No (N)'	System	02 Oct 2020 22:27:57

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:06

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:27:45', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '176f62ba-c382-4e93-a759-cf3c80715de2'	System	02 Oct 2020 22:27:57
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 22:27:57

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:27:54', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '176f62ba-c382-4e93-a759-cf3c80715de2'	System	02 Oct 2020 22:27:57
User entered '02 Oct 2020 18:27'	System	02 Oct 2020 22:27:57

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 3'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:06

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:50:03', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'e7feace4-680c-4bee-bcfb-8609d70e8672'	System	03 Oct 2020 19:50:27
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 19:50:27

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:50:11', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'e7feace4-680c-4bee-bcfb-8609d70e8672'	System	03 Oct 2020 19:50:27
User entered 'No (N)'	System	03 Oct 2020 19:50:27

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:50:18', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'e7feace4-680c-4bee-bcfb-8609d70e8672'	System	03 Oct 2020 19:50:27
User entered 'No (N)'	System	03 Oct 2020 19:50:27

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:06

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:50:22', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'e7feace4-680c-4bee-bcfb-8609d70e8672'	System	03 Oct 2020 19:50:27
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 19:50:27

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:50:25', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'e7feace4-680c-4bee-bcfb-8609d70e8672'	System	03 Oct 2020 19:50:27
User entered '03 Oct 2020 15:50'	System	03 Oct 2020 19:50:27

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 4'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:06

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:04:56', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'd5910e0f-e1b0-42ca-8bb7-3a421e875570'	System	04 Oct 2020 23:05:37
User entered 'None (1)'	System	04 Oct 2020 23:05:37

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'd5910e0f-e1b0-42ca-8bb7-3a421e875570'	System	04 Oct 2020 23:05:37
User entered 'No (N)'	System	04 Oct 2020 23:05:37

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:05', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'd5910e0f-e1b0-42ca-8bb7-3a421e875570'	System	04 Oct 2020 23:05:37
User entered 'No (N)'	System	04 Oct 2020 23:05:37

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:06

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:28', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'd5910e0f-e1b0-42ca-8bb7-3a421e875570'	System	04 Oct 2020 23:05:37
User entered 'None (1)'	System	04 Oct 2020 23:05:37

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:33', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'd5910e0f-e1b0-42ca-8bb7-3a421e875570'	System	04 Oct 2020 23:05:37
User entered '04 Oct 2020 19:05'	System	04 Oct 2020 23:05:37

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:06

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 5'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:06

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:28', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a290502e-3cc2-4d66-b3ac-2f645f7418b7'	System	05 Oct 2020 23:36:42
User entered 'None (1)'	System	05 Oct 2020 23:36:42

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:31', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a290502e-3cc2-4d66-b3ac-2f645f7418b7'	System	05 Oct 2020 23:36:42
User entered 'No (N)'	System	05 Oct 2020 23:36:42

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:34', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a290502e-3cc2-4d66-b3ac-2f645f7418b7'	System	05 Oct 2020 23:36:42
User entered 'No (N)'	System	05 Oct 2020 23:36:42

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:06

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:37', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a290502e-3cc2-4d66-b3ac-2f645f7418b7'	System	05 Oct 2020 23:36:42
User entered 'None (1)'	System	05 Oct 2020 23:36:42

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:40', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a290502e-3cc2-4d66-b3ac-2f645f7418b7'	System	05 Oct 2020 23:36:42
User entered '05 Oct 2020 19:36'	System	05 Oct 2020 23:36:42

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 6'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:06

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:07:49', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9a2d64d8-5b0c-425e-8668-aae78e9d2c41'	System	07 Oct 2020 02:08:05
User entered 'None (1)'	System	07 Oct 2020 02:08:05

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:07:52', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9a2d64d8-5b0c-425e-8668-aae78e9d2c41'	System	07 Oct 2020 02:08:05
User entered 'No (N)'	System	07 Oct 2020 02:08:05

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:07:55', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9a2d64d8-5b0c-425e-8668-aae78e9d2c41'	System	07 Oct 2020 02:08:05
User entered 'No (N)'	System	07 Oct 2020 02:08:05

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:06

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:07:58', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9a2d64d8-5b0c-425e-8668-aae78e9d2c41'	System	07 Oct 2020 02:08:05
User entered 'None (1)'	System	07 Oct 2020 02:08:05

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:08:01', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9a2d64d8-5b0c-425e-8668-aae78e9d2c41'	System	07 Oct 2020 02:08:05
User entered '06 Oct 2020 22:08'	System	07 Oct 2020 02:08:05

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 7'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:06

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:10:58', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a730b0a2-af84-414c-b047-e4cd4000d80f' User entered 'None (1)'	System	07 Oct 2020 20:11:15
	System	07 Oct 2020 20:11:15

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:01', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a730b0a2-af84-414c-b047-e4cd4000d80f'	System	07 Oct 2020 20:11:15
User entered 'No (N)'	System	07 Oct 2020 20:11:15

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:05', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a730b0a2-af84-414c-b047-e4cd4000d80f'	System	07 Oct 2020 20:11:15
User entered 'No (N)'	System	07 Oct 2020 20:11:15

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:06

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:10', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a730b0a2-af84-414c-b047-e4cd4000d80f'	System	07 Oct 2020 20:11:15
User entered 'None (1)'	System	07 Oct 2020 20:11:15

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:13', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a730b0a2-af84-414c-b047-e4cd4000d80f' User entered '07 Oct 2020 16:11'	System	07 Oct 2020 20:11:15
	System	07 Oct 2020 20:11:15

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:39', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7f3d71ba-a5ba-4144-a861-9e49cfd3d01a'	System	01 Oct 2020 17:42:11
User entered 'None (0)'	System	01 Oct 2020 17:42:11

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:44', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7f3d71ba-a5ba-4144-a861-9e49cfd3d01a'	System	01 Oct 2020 17:42:11
User entered 'None (0)'	System	01 Oct 2020 17:42:11

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:48', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7f3d71ba-a5ba-4144-a861-9e49cfd3d01a'	System	01 Oct 2020 17:42:11
User entered 'None (0)'	System	01 Oct 2020 17:42:11

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:51', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7f3d71ba-a5ba-4144-a861-9e49cfd3d01a' User entered 'None (0)'	System	01 Oct 2020 17:42:11
	System	01 Oct 2020 17:42:11

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:54', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7f3d71ba-a5ba-4144-a861-9e49cfd3d01a'	System	01 Oct 2020 17:42:11
User entered 'None (0)'	System	01 Oct 2020 17:42:11

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:56', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7f3d71ba-a5ba-4144-a861-9e49cfd3d01a'	System	01 Oct 2020 17:42:11
User entered 'None (0)'	System	01 Oct 2020 17:42:11

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:42:02', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7f3d71ba-a5ba-4144-a861-9e49cfd3d01a'	System	01 Oct 2020 17:42:11
User entered 'No (N)'	System	01 Oct 2020 17:42:11

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:42:07', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7f3d71ba-a5ba-4144-a861-9e49cfd3d01a' User entered '01 Oct 2020 13:42'	System	01 Oct 2020 17:42:11
	System	01 Oct 2020 17:42:11

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 13:24'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 15:54'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:25', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0cbe73da-e499-4e54-a5e7-31ad42370f43'	System	01 Oct 2020 22:43:57
User entered 'None (0)'	System	01 Oct 2020 22:43:57

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:31', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0cbe73da-e499-4e54-a5e7-31ad42370f43'	System	01 Oct 2020 22:43:57
User entered 'None (0)'	System	01 Oct 2020 22:43:57

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:35', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0cbe73da-e499-4e54-a5e7-31ad42370f43'	System	01 Oct 2020 22:43:57
User entered 'None (0)'	System	01 Oct 2020 22:43:57

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:38', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0cbe73da-e499-4e54-a5e7-31ad42370f43'	System	01 Oct 2020 22:43:57
User entered 'None (0)'	System	01 Oct 2020 22:43:57

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:40', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0cbe73da-e499-4e54-a5e7-31ad42370f43'	System	01 Oct 2020 22:43:57
User entered 'None (0)'	System	01 Oct 2020 22:43:57

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:44', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0cbe73da-e499-4e54-a5e7-31ad42370f43'	System	01 Oct 2020 22:43:57
User entered 'None (0)'	System	01 Oct 2020 22:43:57

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:49', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0cbe73da-e499-4e54-a5e7-31ad42370f43'	System	01 Oct 2020 22:43:57
User entered 'No (N)'	System	01 Oct 2020 22:43:57

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:56', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0cbe73da-e499-4e54-a5e7-31ad42370f43'	System	01 Oct 2020 22:43:57
User entered '01 Oct 2020 18:43'	System	01 Oct 2020 22:43:57

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 16:49'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 2'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:28:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '52902544-5e99-4630-90e8-3afb944e6398'	System	02 Oct 2020 22:28:50
User entered 'None (0)'	System	02 Oct 2020 22:28:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:28:07', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '52902544-5e99-4630-90e8-3afb944e6398'	System	02 Oct 2020 22:28:50
User entered 'None (0)'	System	02 Oct 2020 22:28:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:28:11', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '52902544-5e99-4630-90e8-3afb944e6398'	System	02 Oct 2020 22:28:50
User entered 'None (0)'	System	02 Oct 2020 22:28:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:28:14', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '52902544-5e99-4630-90e8-3afb944e6398'	System	02 Oct 2020 22:28:50
User entered 'None (0)'	System	02 Oct 2020 22:28:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:28:17', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '52902544-5e99-4630-90e8-3afb944e6398'	System	02 Oct 2020 22:28:50
User entered 'None (0)'	System	02 Oct 2020 22:28:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:28:26', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '52902544-5e99-4630-90e8-3afb944e6398'	System	02 Oct 2020 22:28:50
User entered 'None (0)'	System	02 Oct 2020 22:28:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:06

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:28:37', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '52902544-5e99-4630-90e8-3afb944e6398'	System	02 Oct 2020 22:28:50
User entered 'No (N)'	System	02 Oct 2020 22:28:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:28:46', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '52902544-5e99-4630-90e8-3afb944e6398'	System	02 Oct 2020 22:28:50
User entered '02 Oct 2020 18:28'	System	02 Oct 2020 22:28:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 3'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:50:29', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '40518677-387b-48d1-9e8d-d90fcb341666'	System	03 Oct 2020 19:51:21
User entered 'None (0)'	System	03 Oct 2020 19:51:21

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:50:34', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '40518677-387b-48d1-9e8d-d90fcb341666'	System	03 Oct 2020 19:51:21
User entered 'None (0)'	System	03 Oct 2020 19:51:21

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:50:43', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '40518677-387b-48d1-9e8d-d90fcb341666'	System	03 Oct 2020 19:51:21
User entered 'None (0)'	System	03 Oct 2020 19:51:21

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:50:47', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '40518677-387b-48d1-9e8d-d90fcb341666'	System	03 Oct 2020 19:51:21
User entered 'None (0)'	System	03 Oct 2020 19:51:21

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:51:02', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '40518677-387b-48d1-9e8d-d90fcb341666'	System	03 Oct 2020 19:51:21
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	03 Oct 2020 19:51:21

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:51:07', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '40518677-387b-48d1-9e8d-d90fcb341666'	System	03 Oct 2020 19:51:21
User entered 'None (0)'	System	03 Oct 2020 19:51:21

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:06

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:51:16', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '40518677-387b-48d1-9e8d-d90fcb341666'	System	03 Oct 2020 19:51:21
User entered 'No (N)'	System	03 Oct 2020 19:51:21

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:51:18', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '40518677-387b-48d1-9e8d-d90fcb341666'	System	03 Oct 2020 19:51:21
User entered '03 Oct 2020 15:51'	System	03 Oct 2020 19:51:21

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:06

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 4'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:40', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8693abbd-efa0-4f23-aa8d-1ce0ddf2ba0b'	System	04 Oct 2020 23:06:01
User entered 'None (0)'	System	04 Oct 2020 23:06:01

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:43', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8693abbd-efa0-4f23-aa8d-1ce0ddf2ba0b'	System	04 Oct 2020 23:06:01
User entered 'None (0)'	System	04 Oct 2020 23:06:01

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:46', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8693abbd-efa0-4f23-aa8d-1ce0ddf2ba0b'	System	04 Oct 2020 23:06:01
User entered 'None (0)'	System	04 Oct 2020 23:06:01

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:49', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8693abbd-efa0-4f23-aa8d-1ce0ddf2ba0b' User entered 'None (0)'	System	04 Oct 2020 23:06:01

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:52', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8693abbd-efa0-4f23-aa8d-1ce0ddf2ba0b'	System	04 Oct 2020 23:06:01
User entered 'None (0)'	System	04 Oct 2020 23:06:01

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:54', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8693abbd-efa0-4f23-aa8d-1ce0ddf2ba0b'	System	04 Oct 2020 23:06:01
User entered 'None (0)'	System	04 Oct 2020 23:06:01

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:06

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:58', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8693abbd-efa0-4f23-aa8d-1ce0ddf2ba0b'	System	04 Oct 2020 23:06:01
User entered 'No (N)'	System	04 Oct 2020 23:06:01

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:06:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8693abbd-efa0-4f23-aa8d-1ce0ddf2ba0b' User entered '04 Oct 2020 19:06'	System	04 Oct 2020 23:06:01
	System	04 Oct 2020 23:06:01

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:06

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 5'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:44', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9950eb05-4372-44e4-943d-bebd3816ad04'	System	05 Oct 2020 23:37:24
User entered 'None (0)'	System	05 Oct 2020 23:37:24

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:48', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9950eb05-4372-44e4-943d-bebd3816ad04'	System	05 Oct 2020 23:37:24
User entered 'None (0)'	System	05 Oct 2020 23:37:24

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:54', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9950eb05-4372-44e4-943d-bebd3816ad04'	System	05 Oct 2020 23:37:24
User entered 'Some interference with activity (2)'	System	05 Oct 2020 23:37:24

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:37:05', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9950eb05-4372-44e4-943d-bebd3816ad04'	System	05 Oct 2020 23:37:24
User entered 'None (0)'	System	05 Oct 2020 23:37:24

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:37:07', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9950eb05-4372-44e4-943d-bebd3816ad04'	System	05 Oct 2020 23:37:24
User entered 'None (0)'	System	05 Oct 2020 23:37:24

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:37:09', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9950eb05-4372-44e4-943d-bebd3816ad04'	System	05 Oct 2020 23:37:24
User entered 'None (0)'	System	05 Oct 2020 23:37:24

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:06

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:37:12', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9950eb05-4372-44e4-943d-bebd3816ad04'	System	05 Oct 2020 23:37:24
User entered 'No (N)'	System	05 Oct 2020 23:37:24

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:37:21', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9950eb05-4372-44e4-943d-bebd3816ad04'	System	05 Oct 2020 23:37:24
User entered '05 Oct 2020 19:37'	System	05 Oct 2020 23:37:24

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:06

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 6'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:08:05', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '3f1a68b2-fae6-4434-b755-8f190626a44d'	System	07 Oct 2020 02:08:47
User entered 'None (0)'	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:08:08', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '3f1a68b2-fae6-4434-b755-8f190626a44d'	System	07 Oct 2020 02:08:47
User entered 'None (0)'	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:08:21', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '3f1a68b2-fae6-4434-b755-8f190626a44d'	System	07 Oct 2020 02:08:47
User entered 'No interference with activity (1)'	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:08:27', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '3f1a68b2-fae6-4434-b755-8f190626a44d'	System	07 Oct 2020 02:08:47
User entered 'None (0)'	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:08:30', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '3f1a68b2-fae6-4434-b755-8f190626a44d'	System	07 Oct 2020 02:08:47
User entered 'None (0)'	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:08:32', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '3f1a68b2-fae6-4434-b755-8f190626a44d'	System	07 Oct 2020 02:08:47
User entered 'None (0)'	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:06

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:08:43', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '3f1a68b2-fae6-4434-b755-8f190626a44d'	System	07 Oct 2020 02:08:47
User entered 'No (N)'	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:08:45', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '3f1a68b2-fae6-4434-b755-8f190626a44d' User entered '06 Oct 2020 22:08'	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:06

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 7'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:06

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:20', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '6eb16eff-43f7-4809-a53f-e7be253ebff9'	System	07 Oct 2020 20:11:55
User entered 'None (0)'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:06

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:25', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '6eb16eff-43f7-4809-a53f-e7be253ebff9'	System	07 Oct 2020 20:11:55
User entered 'Some interference with activity (2)'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:36', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '6eb16eff-43f7-4809-a53f-e7be253ebff9'	System	07 Oct 2020 20:11:55
User entered 'No interference with activity (1)'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:39', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '6eb16eff-43f7-4809-a53f-e7be253ebff9' User entered 'None (0)'	System	07 Oct 2020 20:11:55
	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:41', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '6eb16eff-43f7-4809-a53f-e7be253ebff9'	System	07 Oct 2020 20:11:55
User entered 'None (0)'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:06

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:44', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '6eb16eff-43f7-4809-a53f-e7be253ebff9'	System	07 Oct 2020 20:11:55
User entered 'None (0)'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:06

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:50', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '6eb16eff-43f7-4809-a53f-e7be253ebff9'	System	07 Oct 2020 20:11:55
User entered 'No (N)'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:52', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '6eb16eff-43f7-4809-a53f-e7be253ebff9'	System	07 Oct 2020 20:11:55
User entered '07 Oct 2020 16:11'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:15:06

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 20:11:55
User entered 'Day 8'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:15:06

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:53:28', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92cf819f-0084-49b7-ac54-85f9fe623ed9'	System	08 Oct 2020 23:53:45
User entered 'Some interference with activity (2)'	System	08 Oct 2020 23:53:45

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:53:43', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92cf819f-0084-49b7-ac54-85f9fe623ed9'	System	08 Oct 2020 23:53:45
User entered '08 Oct 2020 19:53'	System	08 Oct 2020 23:53:45

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 20:11:55
User entered 'Day 9'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 11:15:06

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-09T19:30:22', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'f59dccc3-8ada-4c53-9519-34f87b12becf'	System	09 Oct 2020 23:30:32
User entered 'No interference with activity (1)'	System	09 Oct 2020 23:30:32

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-09T19:30:28', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'f59dccc3-8ada-4c53-9519-34f87b12becf' User entered '09 Oct 2020 19:30'	System	09 Oct 2020 23:30:32
	System	09 Oct 2020 23:30:32

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 23:53:45
User entered 'Day 10'	System	08 Oct 2020 23:53:45

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 11:15:06

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-10T19:59:23', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '01fd513b-7572-4cc2-946f-eb5c4acb8d9d'	System	10 Oct 2020 23:59:29
User entered 'None (0)'	System	10 Oct 2020 23:59:29

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 11:15:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-10T19:59:27', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '01fd513b-7572-4cc2-946f-eb5c4acb8d9d'	System	10 Oct 2020 23:59:29
User entered '10 Oct 2020 19:59'	System	10 Oct 2020 23:59:29

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 23:53:45

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 23:53:45

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 02:08:47
User entered 'Day 8'	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:15:06

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:54:24', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '39ead37e-af7d-48ba-9362-e4fb7444e151'	System	08 Oct 2020 23:54:40
User entered 'Some interference with activity (2)'	System	08 Oct 2020 23:54:40

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:15:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:54:36', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '39ead37e-af7d-48ba-9362-e4fb7444e151'	System	08 Oct 2020 23:54:40
User entered '08 Oct 2020 19:54'	System	08 Oct 2020 23:54:40

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 20:11:55
User entered 'Day 9'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 11:15:06

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-09T19:30:33', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'fb1a60ff-b098-46e1-ab2d-c58f300ba37b'	System	09 Oct 2020 23:30:42
User entered 'None (0)'	System	09 Oct 2020 23:30:42

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 11:15:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-09T19:30:41', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'fb1a60ff-b098-46e1-ab2d-c58f300ba37b'	System	09 Oct 2020 23:30:42
User entered '09 Oct 2020 19:30'	System	09 Oct 2020 23:30:42

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 02:07:44
User entered 'Day 8'	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:15:06

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:54:43', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7137ec4b-193e-4119-aae5-455de7d71c69'	System	08 Oct 2020 23:54:50
User entered 'No (N)'	System	08 Oct 2020 23:54:50

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:15:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:54:47', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7137ec4b-193e-4119-aae5-455de7d71c69'	System	08 Oct 2020 23:54:50
User entered '08 Oct 2020 19:54'	System	08 Oct 2020 23:54:50

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 20:10:54
User entered 'Day 9'	System	07 Oct 2020 20:10:54

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:15:06

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-09T19:30:49', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '890b85d3-a3e3-45f9-9a25-4cd6f76836b0'	System	09 Oct 2020 23:30:54
User entered 'No (N)'	System	09 Oct 2020 23:30:54

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:15:06

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-09T19:30:51', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '890b85d3-a3e3-45f9-9a25-4cd6f76836b0'	System	09 Oct 2020 23:30:54
User entered '09 Oct 2020 19:30'	System	09 Oct 2020 23:30:54

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:15:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:10:54

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:15:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:10:54

US3742477

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 21:54:17

US3742477

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 21:54:17

US3742477

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Oct 2020 21:54:17

US3742477

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:54:17

US3742477

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 21:54:28

US3742477

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 21:54:28

US3742477

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 21:55:43

US3742477

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 21:55:43

US3742477

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Oct 2020 21:55:43

US3742477

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:55:43

US3742477

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 21:55:50

US3742477

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 21:55:50

US3742477

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	05 Nov 2020 19:56:04
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	29 Oct 2020 21:58:19
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 21:58:19

US3742477

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:19

US3742477

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Hassan Haji (b) (4) (b) (4)	05 Nov 2020 19:56:04
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 21:58:19

US3742477

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Hassan Haji (b) (4) (b) (4)	05 Nov 2020 19:56:04
User entered 'Participant in Convalescent phase'	(b) (4), (b) (6) (b) (4)	29 Oct 2020 21:58:19

US3742477

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 21:58:30

US3742477

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 21:58:30

US3742477

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 21:58:38

US3742477

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:38

US3742477

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:38

US3742477

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	29 Oct 2020 21:58:38

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 21:58:57

US3742477

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:58:57

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 21:59:05

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

[If No, reason not given](#)

Audit	User	Time (GMT)
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		30 Oct 2020 16:31:07
User entered 'Confirmed COVID-19 (COVID)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	30 Oct 2020 16:31:07
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	29 Oct 2020 21:59:05
User entered empty.	System	29 Oct 2020 21:59:05
	(b) (4), (b) (6)	

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

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)	29 Oct 2020 21:59:05

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:59:05

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:59:05

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:59:05

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:59:05

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:59:05

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:59:05

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:59:05

US3742477

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 21:59:10

US3742477

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:59:10

US3742477

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:59:10

US3742477

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:59:10

US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:59:19

US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:06

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	29 Oct 2020 21:59:19

US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 21:59:19

US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:06

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:59:19

US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:59:19

US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:06

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	29 Oct 2020 21:59:19

US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 21:59:19

US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:06

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:59:19

US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:59:19

US3742477

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 21:59:25

US3742477

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 21:59:25

US3742477

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 22:07:34

US3742477

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:07:34

US3742477

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 22:07:34

US3742477

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Participant in Convalescent period'	(b) (4), (b) (6)	29 Oct 2020 22:07:34

US3742477

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 22:07:46

US3742477

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 22:07:46

US3742477

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	24 Nov 2020 15:28:09
	(b) (4)	

US3742477

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:28:09
	(b) (4)	

US3742477

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:28:09
	(b) (4)	

US3742477

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:28:09
	(b) (4)	

US3742477

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	(b) (4) 24 Nov 2020 15:29:34
User entered 'No (N)'	Sherry McCammon (b) (4)	(b) (4) 24 Nov 2020 15:28:15

US3742477

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 15:29:34
User entered empty.	System	24 Nov 2020 15:28:15

US3742477

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	24 Nov 2020 15:30:12
	(b) (4)	

US3742477

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:30:12
	(b) (4)	

US3742477

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:30:12
	(b) (4)	

US3742477

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:30:12
	(b) (4)	

US3742477

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Nov 2020 15:30:18
	(b) (4)	

US3742477

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 15:30:18

US3742477

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Nov 2020 15:30:30
	(b) (4)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Sherry McCammon (b) (4)	24 Nov 2020 15:30:30
	(b) (4)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	24 Nov 2020 15:30:30
	(b) (4)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	24 Nov 2020 15:30:30

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46
	(b) (4)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46
	(b) (4)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '13:47'	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46
	(b) (4)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '23 Nov 2020 13:47'	System	24 Nov 2020 15:31:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '098.1' F	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46
	(b) (4)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46
	(b) (4)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46
	(b) (4)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Pulse reported is out of range < 45 System or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		24 Nov 2020 16:19:01
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	24 Nov 2020 16:19:01
User entered '78' reason for change: Data Entry Error	Sherry McCammon (b) (4)	24 Nov 2020 16:19:01
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	24 Nov 2020 15:31:46
User entered '016'	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Nov 2020 15:31:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '16'	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46
	(b) (4)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Nov 2020 15:31:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '116'	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46
	(b) (4)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Nov 2020 15:31:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '070'	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46
	(b) (4)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Nov 2020 15:31:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Nov 2020 15:33:15
	(b) (4)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Sherry McCammon (b) (4)	24 Nov 2020 15:33:15
	(b) (4)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Nov 2020 15:30:46
	(b) (4)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Sherry McCammon (b) (4)	24 Nov 2020 15:30:46
	(b) (4)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:20'	Sherry McCammon (b) (4)	24 Nov 2020 15:30:46
	(b) (4)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '23 Nov 2020 14:20'	System	24 Nov 2020 15:30:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Nov 2020 15:33:36
	(b) (4)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 15:33:36

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '03 Dec 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '07 Dec 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:06

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:33:22
User entered '19 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 16:46:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:06

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:33:22
User entered '10:00'	(b) (4), (b) (6)	23 Oct 2020 16:46:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:06

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 10:00'	System	23 Oct 2020 16:46:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:06

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:33:22
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4), (b) (6)	23 Oct 2020 16:46:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:06

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:33:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 16:46:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '14 Oct 2020'	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 18:06:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 19:17:12
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 19:17:12
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:15:06

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '15 Oct 2020'	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 18:08:11

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered 'None (None)'	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Severe (Severe)' reason for change:	Sherry McCammon (b) (4)	09 Nov 2020 17:59:29
Data Entry Error	(b) (4)	
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:15:06

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '16 Oct 2020'	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 18:11:33

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered 'None (None)'	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:15:06

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '17 Oct 2020'	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 18:13:53

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered 'None (None)'	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:15:06

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '18 Oct 2020'	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 18:18:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered 'None (None)'	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 18:18:46
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 18:18:46
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 18:18:46
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 18:18:46
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:15:06

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '19 Oct 2020'	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '98'	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Oct 2020 18:19:44

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '98.6' F	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:15:06

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:19:44

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	(b) (4) 27 Oct 2020 18:53:36
User entered 'Day 6 (Day 6)'	Sherry McCammon (b) (4)	(b) (4) 27 Oct 2020 18:50:45

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '20 Oct 2020'	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '98'	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	27 Oct 2020 18:50:45

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '98.2' F	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)'	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:15:06

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 18:58:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 18:58:17
User entered '21 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 18:53:36
User entered empty.	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '100' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	27 Oct 2020 18:58:17
User entered empty.	System	27 Oct 2020 18:53:36

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '99.3' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:15:06

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '22 Oct 2020'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '95'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	27 Oct 2020 19:02:32

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '98.7' F	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:15:06

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:02:32
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '23 Oct 2020'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '97'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	27 Oct 2020 19:06:01

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '100.8' F	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:15:06

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:06:01
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '24 Oct 2020'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '100'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '98.2' F	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:15:06

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:08:24
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '25 Oct 2020'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '96'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '97.7' F	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:15:06

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4)	27 Oct 2020 19:11:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:06

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:33
User entered '19 Oct 2020'	Sherry McCammon (b) (4)	23 Oct 2020 17:50:08
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:06

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:33
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Oct 2020 17:50:08
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:06

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:33
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 05:35:08
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'completed' (Site from System).	Sherry McCammon (b) (4)	23 Oct 2020 17:50:33
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	23 Oct 2020 17:50:08
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Oct 2020 17:50:08

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:06

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:33
User entered '19 Oct 2020'	Sherry McCammon (b) (4)	23 Oct 2020 17:50:08
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:06

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:33
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Sherry McCammon (b) (4)	23 Oct 2020 17:50:08

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:06

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:33
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:50:08
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:06

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:33
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:50:43
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Oct 2020 17:50:08

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:06

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:33
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 17:50:43
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 17:50:08
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:50:08

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:06

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:33
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 17:50:43
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 17:50:08
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:50:08

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:15:06

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 17:50:08

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User closed query 'Per CDM: Please clarify what is meant by entered in error. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:19:52
Query 'Per CDM: Please clarify what is meant by entered in error. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 14:40:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 14:46:51
User opened query 'Per CDM: Please clarify what is meant by entered in error. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:46:46
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	Sherry McCammon (b) (4)	23 Oct 2020 17:59:08
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 17:59:00
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:59:00
User entered 'No (N)'	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User closed query 'Per ETRTR: Please complete data entry in this page (page required for confirmed SARS-COV2-positive), thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 16:03:20
Query 'Per ETRTR: Please complete data entry in this page (page required for confirmed SARS-COV2-positive), thanks.' answered with 'completed' (Site from CRA).	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:54
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User opened query 'Per ETRTR: Please complete data entry in this page (page required for confirmed SARS-COV2-positive), thanks.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 22:32:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 14:46:53
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	Sherry McCammon (b) (4)	23 Oct 2020 17:59:27
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 17:58:21
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

Did the subject have Oxygen Saturation of SpO2 $\leq$ 93% on room air at sea level?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 14:46:55
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	Sherry McCammon (b) (4)	23 Oct 2020 17:59:29
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Oct 2020 17:58:21
User entered empty.	System	23 Oct 2020 17:58:21
	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)'	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 14:47:00
User opened query 'Data is required. Please complete.' (Site from System).	Sherry McCammon (b) (4)	23 Oct 2020 17:59:44
User entered empty.	(b) (4)	
	System	23 Oct 2020 17:58:21
	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 14:47:01
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	Sherry McCammon (b) (4)	23 Oct 2020 17:59:50
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	23 Oct 2020 17:58:21
	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 14:47:06
User opened query 'Data is required. Please complete.' (Site from System).	Sherry McCammon (b) (4)	23 Oct 2020 18:00:16
User entered empty.	(b) (4)	
	System	23 Oct 2020 17:58:21
	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:15:06

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:15:06

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:35
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:52:14

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:15:06

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:15:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	05 Nov 2020 15:03:30
	(b) (4)	

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:15:06

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered '21 Oct 2020'	Kaitlin Mason (b) (4)	05 Nov 2020 15:03:30
	(b) (4)	

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:15:06

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:15:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	05 Nov 2020 15:03:30
	(b) (4)	

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:15:06

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered '23 Oct 2020'	Kaitlin Mason (b) (4)	05 Nov 2020 15:03:30
	(b) (4)	

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:15:06

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:15:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	05 Nov 2020 15:03:30
	(b) (4)	

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:15:06

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered '26 Oct 2020'	Kaitlin Mason (b) (4)	05 Nov 2020 15:03:30
	(b) (4)	

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:15:06

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:15:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	05 Nov 2020 15:03:30
	(b) (4)	

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:15:06

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered '27 Oct 2020'	Kaitlin Mason (b) (4)	05 Nov 2020 15:03:30
	(b) (4)	

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:15:06

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:15:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	05 Nov 2020 15:03:30
	(b) (4)	

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:15:06

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered '02 Nov 2020'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:15:06

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:15:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:09:50
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09NOV2020 for Day 21 is reported under Illness visit in PPD central lab, however sample details are not recorded in EDC. Please update as appropriate, thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 05:21:42
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09NOV2020 for Day 21 is reported under Illness visit in PPD central lab, however sample details are not recorded in EDC. Please update as appropriate, thank you.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	18 Nov 2020 15:10:43
DataPoint Un-verified.	Kaitlin Mason (b) (4) (b) (4)	18 Nov 2020 15:10:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	18 Nov 2020 15:10:38
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09NOV2020 for Day 21 is reported under Illness visit in PPD central lab, however sample details are not recorded in EDC. Please update as appropriate, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:09:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:27:34
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:03:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 15:03:42
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:42
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:03:30
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:15:06

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:09:50
DataPoint Un-verified.	Kaitlin Mason (b) (4)	18 Nov 2020 15:10:38
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 15:10:38
DataPoint Verified.	Kaitlin Mason (b) (4)	18 Nov 2020 15:10:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered empty.	(b) (4)	
	Kaitlin Mason (b) (4)	05 Nov 2020 15:03:30
	(b) (4)	

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:15:06

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:15:06

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:27:34
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:03:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 15:03:42
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 15:03:42
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:03:30
User entered empty.	Kaitlin Mason (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:15:06

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered empty.	Kaitlin Mason (b) (4)	05 Nov 2020 15:03:30
	(b) (4)	

US3742477

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:26:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 19:48:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:40:33
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	Sherry McCammon (b) (4)	23 Oct 2020 17:23:26
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 17:23:18
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:23:18
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Oct 2020 17:02:34

US3742477

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:26:15
User closed query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 16:02:56
Query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' answered with 'completed' (Site from CRA).	Kaitlin Mason (b) (4)	05 Nov 2020 15:06:37
User opened query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 22:21:03
User entered '19 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:40:33
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:23:18
User entered '19 Oct 2020'	Sherry McCammon (b) (4)	23 Oct 2020 17:02:34

US3742477

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:26:15
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:40:33
User entered empty; reason for change Data Entry Error	(b) (4)	23 Oct 2020 17:23:18
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	23 Oct 2020 17:02:34
	(b) (4)	

US3742477

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	23 Oct 2020 17:40:33
User entered empty.	System	23 Oct 2020 17:23:18
User entered 'SICKD1'	System	23 Oct 2020 17:02:34

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 19:49:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:41:39
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	Sherry McCammon (b) (4)	23 Oct 2020 17:25:05
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 17:24:56
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:24:56
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Oct 2020 17:03:46

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:53
User entered '19 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:41:39
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:24:56
User entered '19 Oct 2020'	Sherry McCammon (b) (4)	23 Oct 2020 17:03:46

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:53
User entered '12:28' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:41:39
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:24:56
User entered '12:28'	Sherry McCammon (b) (4)	23 Oct 2020 17:03:46

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:28'	System	23 Oct 2020 17:41:39
User entered empty.	System	23 Oct 2020 17:24:56
User entered '19 Oct 2020 12:28'	System	23 Oct 2020 17:03:46

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:53
User closed query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	System	23 Oct 2020 17:41:39
Query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' answered by data change (Site from System).	System	23 Oct 2020 17:41:39
User entered '155' cm reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:41:39
DataPoint set to visible.	(b) (4)	
DataPoint set to invisible.	System	23 Oct 2020 17:40:33
User opened query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	System	23 Oct 2020 17:23:18
User entered '155' in	System	23 Oct 2020 17:03:46
DataPoint set to visible.	Sherry McCammon (b) (4)	23 Oct 2020 17:03:46
	(b) (4)	
	System	23 Oct 2020 17:02:34

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:53
DataPoint set to visible.	System	23 Oct 2020 17:40:33
DataPoint set to invisible.	System	23 Oct 2020 17:23:18
User entered '226.8' lb	Sherry McCammon (b) (4)	23 Oct 2020 17:03:46
DataPoint set to visible.	(b) (4)	23 Oct 2020 17:02:34

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:53
User entered '98.6' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:41:39
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:24:56
User entered '98.6' F	Sherry McCammon (b) (4)	23 Oct 2020 17:03:46

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:53
User entered 'Oral (Oral)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:41:39
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 17:24:56
	(b) (4)	
User entered 'Oral (Oral)'	Sherry McCammon (b) (4)	23 Oct 2020 17:03:46
	(b) (4)	

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:53
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 17:03:46
	(b) (4)	

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:53
User entered '78' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:41:39
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 17:24:56
	(b) (4)	
User entered '78'	Sherry McCammon (b) (4)	23 Oct 2020 17:03:46
	(b) (4)	

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Oct 2020 17:41:39
User entered empty.	System	23 Oct 2020 17:24:56
User entered 'bpm'	System	23 Oct 2020 17:03:46

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:53
User entered '17' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:41:39
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 17:24:56
	(b) (4)	
User entered '17'	Sherry McCammon (b) (4)	23 Oct 2020 17:03:46
	(b) (4)	

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Oct 2020 17:41:39
User entered empty.	System	23 Oct 2020 17:24:56
User entered 'breaths/min'	System	23 Oct 2020 17:03:46

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:53
User entered '110' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:41:39
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 17:24:56
	(b) (4)	
User entered '110'	Sherry McCammon (b) (4)	23 Oct 2020 17:03:46
	(b) (4)	

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Oct 2020 17:41:39
User entered empty.	System	23 Oct 2020 17:24:56
User entered 'mmHg'	System	23 Oct 2020 17:03:46

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:53
User entered '69' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:41:39
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 17:24:56
	(b) (4)	
User entered '69'	Sherry McCammon (b) (4)	23 Oct 2020 17:03:46
	(b) (4)	

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Oct 2020 17:41:39
User entered empty.	System	23 Oct 2020 17:24:56
User entered 'mmHg'	System	23 Oct 2020 17:03:46

US3742477

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:25:09
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Oct 2020 17:39:47
	(b) (4)	

US3742477

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:25:09
User entered '19 Oct 2020'	Sherry McCammon (b) (4)	23 Oct 2020 17:39:47
	(b) (4)	

US3742477

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:15:06

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:25:47
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:40:09

US3742477

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:15:06

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:25:47
User entered '19 Oct 2020'	Sherry McCammon (b) (4)	23 Oct 2020 17:40:09
	(b) (4)	

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Nov 2020 15:49:43
	(b) (4)	

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Sherry McCammon (b) (4)	24 Nov 2020 15:49:43
	(b) (4)	

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	24 Nov 2020 15:49:43
	(b) (4)	

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:06

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	24 Nov 2020 15:49:43

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Nov 2020 15:51:45
	(b) (4)	

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Sherry McCammon (b) (4)	24 Nov 2020 15:51:45
	(b) (4)	

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '13:47'	Sherry McCammon (b) (4)	24 Nov 2020 15:51:45
	(b) (4)	

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '23 Nov 2020 13:47'	System	24 Nov 2020 15:51:45

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

Height (xxx.x)

Audit	User	Time (GMT)
User entered '62.0' in	Sherry McCammon (b) (4)	24 Nov 2020 15:51:45
DataPoint set to visible.	(b) (4) System	24 Nov 2020 15:49:43

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '225.7' lb	Sherry McCammon (b) (4)	24 Nov 2020 15:51:45
DataPoint set to visible.	(b) (4) System	24 Nov 2020 15:49:43

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '098.1' F	Sherry McCammon (b) (4)	24 Nov 2020 15:51:45
	(b) (4)	

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Sherry McCammon (b) (4)	24 Nov 2020 15:51:45
	(b) (4)	

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:51:45
	(b) (4)	

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '081'	Sherry McCammon (b) (4)	24 Nov 2020 15:51:45
	(b) (4)	

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Nov 2020 15:51:45

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '16'	Sherry McCammon (b) (4)	24 Nov 2020 15:51:45
	(b) (4)	

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Nov 2020 15:51:45

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '116'	Sherry McCammon (b) (4)	24 Nov 2020 15:51:45
	(b) (4)	

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Nov 2020 15:51:45

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '70'	Sherry McCammon (b) (4)	24 Nov 2020 15:51:45
	(b) (4)	

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Nov 2020 15:51:45

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Nov 2020 15:50:22
	(b) (4)	

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Sherry McCammon (b) (4)	24 Nov 2020 15:50:22
	(b) (4)	

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:15:06

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Nov 2020 15:52:49
	(b) (4)	

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 11:15:06

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Sherry McCammon (b) (4)	24 Nov 2020 15:52:49
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:15:06

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:19
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:59

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 23:30:02
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Symptom lasted less than 48 hours - participant was brought in for illness visit at a later date' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	18 Nov 2020 20:45:23
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 20:13:06
User closed query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (NASAL CONGESTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 21:40:13
Query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (NASAL CONGESTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.' answered with 'nasal congestion is different than rhinorrhea and thus will remain separate ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	09 Nov 2020 17:27:54
User opened query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (NASAL CONGESTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:45:34
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Rhinorrhea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:34:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:34:47
Data point term sent to Coder	System	20 Oct 2020 18:33:57

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'rhinorrhea'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 21:40:15
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4)	09 Nov 2020 17:29:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 17:29:51
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:45:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 19:20:52
User entered 'No (N)'	Hassan Haji (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '07 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	06 Nov 2020 16:31:05
User entered '7 Oct 2020'	Hassan Haji (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '07 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	06 Nov 2020 16:31:05
User entered '7 Oct 2020'	Hassan Haji (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[None](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 18:35:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 18:35:34
Data point term sent to Coder	System	20 Oct 2020 18:34:59
User entered 'nasal congestion'	Hassan Haji (b) (4)	20 Oct 2020 18:34:30
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 21:40:27
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4)	09 Nov 2020 17:30:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 17:30:36
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:43:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 19:20:41
User entered 'No (N)'	Hassan Haji (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '7 Oct 2020'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[None](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Adverse event](#)

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: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 18:36:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 18:36:40
Data point term sent to Coder	System	20 Oct 2020 18:36:01
User entered 'bilateral shoulder pain'	Hassan Haji (b) (4)	20 Oct 2020 18:35:59
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Oct 2020 16:52:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:52:10
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 16:52:10
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:35:59
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Oct 2020 16:52:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:52:10
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 16:52:10
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:35:59
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Oct 2020 16:52:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:52:10
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 16:52:10
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:35:59
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 15:00:09
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Oct 2020 16:52:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:52:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	24 Oct 2020 16:52:10
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:35:59
User entered empty.	Hassan Haji (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 15:00:09
User entered empty.	Hassan Haji (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Oct 2020 16:52:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:52:10
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 16:52:10
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:35:59
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Oct 2020 16:52:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:52:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 16:52:10
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:35:59
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Oct 2020 16:52:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:52:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 16:52:10
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:35:59
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Oct 2020 16:52:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:52:10
User entered 'None (NONE)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 16:52:10
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:35:59
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[None](#)

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Oct 2020 16:52:10
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	24 Oct 2020 16:52:10
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	20 Oct 2020 18:35:59
User entered '0'	Hassan Haji (b) (4)	20 Oct 2020 18:35:59
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 15:00:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 15:00:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	09 Nov 2020 15:00:09
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:35:59
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	24 Oct 2020 16:52:10

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Oct 2020 16:52:10

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in elbow - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:37:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:37:49
Data point term sent to Coder	System	20 Oct 2020 18:37:05
User entered 'left elbow pain'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Oct 2020 16:54:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:54:42
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 16:54:42
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:36:45
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Oct 2020 16:54:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:54:42
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 16:54:42
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:36:45
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Oct 2020 16:54:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:54:42
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 16:54:42
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:36:45
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 15:01:53
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Oct 2020 16:54:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:54:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	24 Oct 2020 16:54:42
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:36:45
User entered empty.	Hassan Haji (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 15:01:53
User entered empty.	Hassan Haji (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Oct 2020 16:54:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:54:42
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 16:54:42
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:36:45
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Oct 2020 16:54:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:54:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 16:54:42
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:36:45
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Oct 2020 16:54:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:54:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 16:54:42
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:36:45
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Oct 2020 16:54:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:54:42
User entered 'None (NONE)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 16:54:42
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:36:45
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[None](#)

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Oct 2020 16:54:42
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	24 Oct 2020 16:54:42
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	20 Oct 2020 18:36:45
User entered '0'	Hassan Haji (b) (4)	20 Oct 2020 18:36:45
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 15:01:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 15:01:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 15:01:53
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:36:45
User entered empty.	Hassan Haji (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Oct 2020 16:54:42

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Oct 2020 16:54:42

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:14
User entered 'USA-US127-2020-mRNA-1273-P301000006'	System	26 Oct 2020 21:00:09
User entered 'New'	(b) (4), (b) (6)	26 Oct 2020 21:00:09

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 21:38:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 21:38:22
Data point term sent to Coder	System	23 Nov 2020 20:59:26
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.	Coder Import (b) (4)	23 Nov 2020 20:59:11
' canceled (Site from System).		
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.	Coder Import (b) (4)	23 Nov 2020 12:24:06
' (Site from System).		
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 18:34:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 18:34:41
Data point term sent to Coder	System	23 Oct 2020 18:33:21
User entered 'symptomatic covid-19'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:33:03

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: The start date of the event is 14 Oct 2020. Did the subject report any symptoms on that day? If yes, please add those symptoms to 134 Oct 2020 symptom log page. If no, please consider updating start date of the event. ' canceled (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 18:22:36
User opened query 'PV Query: The start date of the event is 14 Oct 2020. Did the subject report any symptoms on that day? If yes, please add those symptoms to 134 Oct 2020 symptom log page. If no, please consider updating start date of the event. ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:30:58
User entered empty.	System	23 Oct 2020 18:33:03

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	(b) (4) 09 Nov 2020 15:05:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	(b) (4) 23 Oct 2020 18:33:03

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '31 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	(b) (4) 09 Nov 2020 15:05:44
User entered empty.	Sherry McCammon (b) (4)	(b) (4) 23 Oct 2020 18:33:03

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (when symptoms have resolved). ' canceled (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 18:22:21
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved). ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:29:16
User entered empty.	System	23 Oct 2020 18:33:03

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	06 Nov 2020 04:58:48
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'withdrawn due to positive covid19' (Site from System).	Kaitlin Mason (b) (4)	05 Nov 2020 14:47:18
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	05 Nov 2020 14:45:52
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:45:52
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	24 Oct 2020 13:23:11
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	24 Oct 2020 13:23:11
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	24 Oct 2020 13:23:11
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	23 Oct 2020 18:36:01
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[None](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[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)	10 Nov 2020 20:30:46
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 'Medication was taken for symptoms' (Site from DM).	Sherry McCammon (b) (4)	09 Nov 2020 15:05:02
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)	06 Nov 2020 14:47:05
User entered '1'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 14:16:31
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' answered with 'recovered' (Site from Safety).	Sherry McCammon (b) (4)	09 Nov 2020 15:05:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 15:05:44
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:30:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 20:08:50
Query 'Data is required. Please complete.' answered with 'DUE TO SARS COV 2 ' (Site from System).	Kaitlin Mason (b) (4)	24 Oct 2020 13:23:16
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 18:33:03
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	07 Nov 2020 01:17:07
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. ' (Site from Safety).	(b) (4), (b) (6)	07 Nov 2020 01:17:05
User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19. ' (Site from Safety).	(b) (4), (b) (6)	07 Nov 2020 01:17:03
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). If no treatment was provided, please state so. ' answered with 'No additional treatment reported' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 14:44:56
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19. ' answered with 'No report of positive contacts' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 14:44:20
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. ' answered with 'participant did not receive second vaccination due to COVID19 illness' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 14:42:47
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). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:30:30

v6.020 DTW (1102)

1903 of 2212

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:29:51
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19. ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:29:33
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:33:03

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	23 Oct 2020 18:33:03

US3742477

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 18:33:03

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Adverse event](#)

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: Pain in extremity, LLT: Pain in arm - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:04:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:04:14
Data point term sent to Coder	System	24 Nov 2020 15:49:19
User entered 'BILATERIAL FOREARM PAIN'	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 15:48:53

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 15:48:53

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 15:48:53

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[None](#)

Audit	User	Time (GMT)
User entered '1'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 15:48:53

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 15:48:53

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:15:06

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please add medication dosing details for AE "Symptomatic COVID-19", thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 21:09:57
Query 'Per ETRTR: Please add medication dosing details for AE "Symptomatic COVID-19", thanks.' answered with 'completed. please refer to concomitant medication #08' (Site from CRA).	(b) (4), (b) (6)	31 Oct 2020 19:48:00
User opened query 'Per ETRTR: Please add medication dosing details for AE "Symptomatic COVID-19", thanks.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 22:19:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 19:39:21

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, PRODUCT: MINERAL SUPPLEMENTS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 13:38:33
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 Oct 2020 13:38:33
Data point term sent to Coder	System	01 Oct 2020 19:41:30
User entered 'K-21 Mineral Supplement'	(b) (4), (b) (6) (b) (4)	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 19:47:09
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'UPDATED' (Site from DM).	Kaitlin Mason (b) (4)	26 Oct 2020 14:43:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 14:43:00
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 17:34:51
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'Supplement'	(b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2'	(b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'tbsp'	(b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'UN Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: PROTEIN SUPPLEMENTS, PRODUCT: PROTEIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 05:15:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 05:15:38
Data point term sent to Coder	System	01 Oct 2020 19:42:35
User entered 'Dietary Protein Supplement'	(b) (4), (b) (6) (b) (4)	01 Oct 2020 19:42:31

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 19:47:15
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'UPDATED' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	26 Oct 2020 14:44:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	26 Oct 2020 14:44:16
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 17:34:59
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'Supplement'	(b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'packet'	(b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'UN May 2020'	(b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 19:42:31

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 19:42:31

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 19:42:31

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: HERBAL PREPARATION - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 14:04:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 14:04:14
User closed query 'Per CDM Re-query: Response is updated, however, the specific herb is not added on the Name of Medication. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	05 Nov 2020 04:16:42
Query 'Per CDM Re-query: Response is updated, however, the specific herb is not added on the Name of Medication. ' answered with 'ENTERED ' (Site from DM).	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 14:02:14
User opened query 'Per CDM Re-query: Response is updated, however, the specific herb is not added on the Name of Medication. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	02 Nov 2020 11:43:25
User closed query 'Per DM CLR: Please review Medication and please update to provide the specific herb taken for constipation. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6) (b) (4)	02 Nov 2020 11:41:26
Query 'Per DM CLR: Please review Medication and please update to provide the specific herb taken for constipation. Please update as appropriate or provide clarification.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6) (b) (4)	31 Oct 2020 20:01:25
User opened query 'Per DM CLR: Please review Medication and please update to provide the specific herb taken for constipation. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6) (b) (4)	30 Oct 2020 19:32:23
Data point term sent to Coder	System	01 Oct 2020 19:43:40
User entered 'Herbal Laxative Tea'	(b) (4), (b) (6) (b) (4)	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH record that match this condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:41:40
Query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH record that match this condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 20:01:37
User opened query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH record that match this condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:32:38
User entered 'Constipation'	(b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 19:43:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 19:43:42
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 19:43:42
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 19:43:33
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'Packet'	(b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	01 Oct 2020 19:43:51
User entered 'UN Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 19:43:51
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	01 Oct 2020 19:43:33
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BECLOMETASONE DIPROPIONATE, PRODUCTSYNONYM: QVAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 23:52:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 23:52:48
Data point term sent to Coder	System	02 Nov 2020 14:03:21
Coding entries removed.	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 14:02:41
User entered 'QVAR INHALER' reason for change: Data Entry Error	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 14:02:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BECLOMETASONE DIPROPIONATE, PRODUCTSYNONYM: QVAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 19:46:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 19:46:57
Data point term sent to Coder	System	01 Oct 2020 19:45:44
User entered 'Qvar'	(b) (4), (b) (6) (b) (4)	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'Asthma'	(b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '80'	(b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review recorded Unit as this is not the expected unit for this medication or for the recorded dose. Please update the unit as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:44:24
Query 'Per DM CLR: Please review recorded Unit as this is not the expected unit for this medication or for the recorded dose. Please update the unit as appropriate or provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 20:03:17
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Oct 2020 20:03:04
User opened query 'Per DM CLR: Please review recorded Unit as this is not the expected unit for this medication or for the recorded dose. Please update the unit as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:32:51
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered 'UN Apr 2017'	(b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:21:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:21:40
Data point term sent to Coder	System	31 Oct 2020 20:06:33
Coding entries removed.	(b) (4), (b) (6)	31 Oct 2020 20:05:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:46:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:46:53
Data point term sent to Coder	System	01 Oct 2020 19:46:45
User entered 'Diclofenac'	(b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH or AE record that match this condition. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:45:39
Query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH or AE record that match this condition. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 20:06:10
User entered 'OSTEOARTHRITIS, KNEE PAIN, JOINT PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Oct 2020 20:05:57
User opened query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH or AE record that match this condition. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:33:31
User entered 'Knee pain, joint pain'	(b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	(b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Oct 2020 19:46:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 19:46:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Oct 2020 19:46:00
User entered 'UN UNK UNKN' (non-conformant).	(b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 14:37:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 14:37:35
Data point term sent to Coder Coding entries removed.	System Sherry McCammon (b) (4) (b) (4)	09 Nov 2020 14:36:38 09 Nov 2020 14:36:34
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:27:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:27:32
Data point term sent to Coder User entered 'ibuprofen'	System Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:40 20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of REACTOGENETIC SYMPTOMS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 15:13:00
Query 'Per DM CLR: Please update the indication to reflect the location and type of REACTOGENETIC SYMPTOMS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Sherry McCammon (b) (4)	09 Nov 2020 14:36:47
User entered 'muscle aches' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 14:36:34
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of REACTOGENETIC SYMPTOMS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:33:29
User entered 'reactogenetic symptoms'	Hassan Haji (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '05 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	06 Nov 2020 16:27:25
User entered '5 Oct 2020'	Hassan Haji (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '07 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	06 Nov 2020 16:27:25
User entered '7 Oct 2020'	Hassan Haji (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

[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: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEP HRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 07:52:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 07:52:33
Data point term sent to Coder	System	20 Oct 2020 18:30:48
User entered 'acetaminophen+dextromethorphan+phenylephrine'	Hassan Haji (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'rhinorrhea and nasal congestion'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if the dose of this medication could be recorded using slash and not plus (e.g. 5/325). If so please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:21:22
Query 'Per DM CLR: Please review if the dose of this medication could be recorded using slash and not plus (e.g. 5/325). If so please update eCRF as appropriate. ' answered with 'CORRECTED' (Site from DM).	Sherry McCammon (b) (4)	06 Nov 2020 16:19:53
User entered '650/20/10' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 16:17:56
User opened query 'Per DM CLR: Please review if the dose of this medication could be recorded using slash and not plus (e.g. 5/325). If so please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:33:18
User entered '650+20+10'	Hassan Haji (b) (4)	20 Oct 2020 18:30:17
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '07 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	06 Nov 2020 16:19:43
User entered '7 Oct 2020'	Hassan Haji (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '07 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	06 Nov 2020 16:19:43
User entered '7 Oct 2020'	Hassan Haji (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

[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 Nov 2020 00:06:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 00:06:39
Data point term sent to Coder	System	09 Nov 2020 14:41:47
Data point term sent to Coder	System	09 Nov 2020 14:40:46
Coding entries removed.	Sherry McCammon (b) (4)	09 Nov 2020 14:39:56
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)	30 Oct 2020 15:36:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 15:36:04
Data point term sent to Coder	System	30 Oct 2020 13:16:46
User entered 'ACETAMENOPHEN'	Sherry McCammon (b) (4)	30 Oct 2020 13:16:20

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	30 Oct 2020 13:16:20
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 15:13:13
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	Sherry McCammon (b) (4)	09 Nov 2020 14:40:58
User entered 'symptomatic covid-19' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 14:40:53
User entered 'rhinorrhea and nasal congestion' reason for change: Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 14:39:56
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:31:34
User entered 'VIRAL SYNDROME WITH COUGH'	Sherry McCammon (b) (4)	30 Oct 2020 13:16:20

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Sherry McCammon (b) (4)	30 Oct 2020 13:16:20
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Sherry McCammon (b) (4)	30 Oct 2020 13:16:20
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 13:16:20
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Sherry McCammon (b) (4)	30 Oct 2020 13:16:20
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 13:16:20
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	30 Oct 2020 13:16:20
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	30 Oct 2020 13:16:20
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '15 Oct 2020'	Sherry McCammon (b) (4)	30 Oct 2020 13:16:20
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	30 Oct 2020 13:16:20
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	(b) (4) 09 Nov 2020 14:41:33
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	(b) (4) 30 Oct 2020 13:16:20

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '30 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	(b) (4) 09 Nov 2020 14:41:33
User entered empty.	Sherry McCammon (b) (4)	(b) (4) 30 Oct 2020 13:16:20

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	(b) (4) 30 Oct 2020 13:16:50
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	(b) (4) 30 Oct 2020 13:16:20

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 13:16:20

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 13:16:20

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 13:16:20

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 14:44:33
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 Nov 2020 14:44:33
Data point term sent to Coder	System	09 Nov 2020 14:43:50
User entered 'ibuprofen'	Sherry McCammon (b) (4) (b) (4)	09 Nov 2020 14:43:44

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Nov 2020 14:43:44
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'symptomatic covid-19'	Sherry McCammon (b) (4)	09 Nov 2020 14:43:44
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '800'	Sherry McCammon (b) (4)	09 Nov 2020 14:43:44
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Sherry McCammon (b) (4)	09 Nov 2020 14:43:44
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	09 Nov 2020 14:43:44
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Sherry McCammon (b) (4)	09 Nov 2020 14:43:44
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	09 Nov 2020 14:43:44
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	09 Nov 2020 14:43:44
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	09 Nov 2020 14:43:44
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Sherry McCammon (b) (4)	09 Nov 2020 14:43:44
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	09 Nov 2020 14:43:44
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Nov 2020 14:43:44
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '25 Oct 2020'	Sherry McCammon (b) (4)	09 Nov 2020 14:43:44
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	09 Nov 2020 14:43:44
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 14:43:44

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 14:43:44

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 14:43:44

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

[Name of Medication](#)

Audit	User	Time (GMT)
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: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 14:48:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 14:48:41
Data point term sent to Coder	System	09 Nov 2020 14:47:58
User entered 'aspirin'	Sherry McCammon (b) (4)	09 Nov 2020 14:47:57

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Nov 2020 14:47:57
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

[Indication](#)

Audit	User	Time (GMT)
User entered 'thrombosis'	Sherry McCammon (b) (4)	09 Nov 2020 14:47:57
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	Sherry McCammon (b) (4)	09 Nov 2020 14:47:57
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Sherry McCammon (b) (4)	09 Nov 2020 14:47:57
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	09 Nov 2020 14:47:57
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	09 Nov 2020 14:47:57
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	09 Nov 2020 14:47:57
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	09 Nov 2020 14:47:57
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sherry McCammon (b) (4)	09 Nov 2020 14:47:57
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Sherry McCammon (b) (4)	09 Nov 2020 14:47:57
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sherry McCammon (b) (4)	09 Nov 2020 14:47:57
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Nov 2020 14:47:57
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '01 Nov 2020'	Sherry McCammon (b) (4)	09 Nov 2020 14:47:57
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Nov 2020 14:47:57
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 14:47:57

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 14:47:57

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Nov 2020 14:47:57

US3742477

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:06

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Sherry McCammon (b) (4)	23 Oct 2020 18:36:01
	(b) (4)	

US3742477

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:06

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Per CDM; Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 23:30:19
Query 'Per CDM; Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	18 Nov 2020 20:44:26
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Per Query Resolution	Kaitlin Mason (b) (4) (b) (4)	18 Nov 2020 20:44:21
User opened query 'Per CDM; Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:48:30
User closed query 'Per CDM: AE #6 SYMPTOMATIC COVID-19 records Action taken with investigational product as Investigational Product Withdrawn However, AE is not sleect as primary reason. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 21:40:45
Query 'Per CDM: AE #6 SYMPTOMATIC COVID-19 records Action taken with investigational product as Investigational Product Withdrawn However, AE is not sleect as primary reason. Please reconcile.' answered with 'Reconciled per query' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 15:37:51
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Per Query Resolution	(b) (4), (b) (6)	09 Nov 2020 15:37:29
User opened query 'Per CDM: AE #6 SYMPTOMATIC COVID-19 records Action taken with investigational product as Investigational Product Withdrawn However, AE is not sleect as primary reason. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:56:57
User entered 'Due to SARS-COV-2 (COVID)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:36:01

US3742477

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:06

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

Audit	User	Time (GMT)
User entered empty; reason for change Per Query Resolution	Kaitlin Mason (b) (4) (b) (4)	18 Nov 2020 20:44:21
User entered 'Symptomatic COVID 19' reason for change: Per Query Resolution	(b) (4), (b) (6) (b) (4)	09 Nov 2020 15:37:29
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	05 Nov 2020 14:46:51
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 14:46:51
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	05 Nov 2020 14:46:39
User entered 'Due to SAE positive COVID19' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 14:46:39
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:36:01

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'USA-US127-2020-MRNA-1273-P301000006'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Karen'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Kotloff'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '685 W. Baltimore Street, HSF 480'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Baltimore'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:14
Un-reviewed for Safety.	System	10 Nov 2020 14:16:56
User entered empty.	System	10 Nov 2020 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:16:46
User entered 'Maryland'	Kaitlin Mason (b) (4)	09 Nov 2020 17:32:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '21201'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Nov 2020 01:17:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
User entered 'US'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	10 Nov 2020 14:16:56
User entered '3'	System	07 Nov 2020 01:27:37
User entered '2'	System	07 Nov 2020 01:17:33
User entered '1'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'USA-US127-2020-MRNA-1273-P301000006'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Karen'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Kotloff'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '685 W. Baltimore Street, HSF 480'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Baltimore'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:14
Un-reviewed for Safety.	System	10 Nov 2020 14:16:56
User entered empty.	System	10 Nov 2020 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:16:46
User entered 'Maryland'	Kaitlin Mason (b) (4)	09 Nov 2020 17:32:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '21201'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Nov 2020 01:17:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
User entered 'US'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	10 Nov 2020 14:16:56
User entered '3'	System	07 Nov 2020 01:27:37
User entered '2'	System	07 Nov 2020 01:17:33
User entered '1'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:15:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
User entered '26/Oct/2020 17:00'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:15:06

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)
Reviewed for Safety.	(b) (4), (b) (6)	07 Nov 2020 01:17:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
User entered '1'	(b) (4), (b) (6)	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'USA-US127-2020-MRNA-1273-P301000006'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Karen'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Kotloff'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '685 W. Baltimore Street, HSF 480'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Baltimore'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:14
Un-reviewed for Safety.	System	10 Nov 2020 14:16:56
User entered empty.	System	10 Nov 2020 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:16:46
User entered 'Maryland'	Kaitlin Mason (b) (4)	09 Nov 2020 17:32:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '21201'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Nov 2020 01:17:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
User entered 'US'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	10 Nov 2020 14:16:56
User entered '3'	System	07 Nov 2020 01:27:37
User entered '2'	System	07 Nov 2020 01:17:33
User entered '1'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:15:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:14
User entered '06/Nov/2020 20:17'	System	07 Nov 2020 01:17:33

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:15:06

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 16:24:14
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:16:46
User entered '1'	(b) (4), (b) (6)	07 Nov 2020 01:17:33

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'USA-US127-2020-MRNA-1273-P301000006'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Karen'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Kotloff'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '685 W. Baltimore Street, HSF 480'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Baltimore'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:14
Un-reviewed for Safety.	System	10 Nov 2020 14:16:56
User entered empty.	System	10 Nov 2020 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:16:46
User entered 'Maryland'	Kaitlin Mason (b) (4)	09 Nov 2020 17:32:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '21201'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Nov 2020 01:17:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
User entered 'US'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	10 Nov 2020 14:16:56
User entered '3'	System	07 Nov 2020 01:27:37
User entered '2'	System	07 Nov 2020 01:17:33
User entered '1'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:15:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:14
User entered '06/Nov/2020 20:27'	System	07 Nov 2020 01:27:37

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:15:06

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 16:24:14
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:16:46
User entered '1'	(b) (4), (b) (6)	07 Nov 2020 01:27:37

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'USA-US127-2020-MRNA-1273-P301000006'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Karen'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Kotloff'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '685 W. Baltimore Street, HSF 480'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Baltimore'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:14
Un-reviewed for Safety.	System	10 Nov 2020 14:16:56
User entered empty.	System	10 Nov 2020 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:16:46
User entered 'Maryland'	Kaitlin Mason (b) (4)	09 Nov 2020 17:32:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '21201'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Nov 2020 01:17:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
User entered 'US'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	10 Nov 2020 14:16:56
User entered '3'	System	07 Nov 2020 01:27:37
User entered '2'	System	07 Nov 2020 01:17:33
User entered '1'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:15:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:14
User entered '10/Nov/2020 09:16'	System	10 Nov 2020 14:16:56

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 11:15:06

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 16:24:14
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 14:16:56