

US3482284 (Prod: Hope Clinic of The Emory Vaccine Center)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:32:40

All time stamps listed in this document are displayed in GMT

US3482284

Form: Participant Creation

Generated On: 26 Nov 2020 09:32:40

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	09 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:40

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	62
Age Units	YEARS
Age (Derived)	62
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:40

Date of Informed Consent (<i>dd MMM yyyy</i>)	9 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☒
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:32:40

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:32:40

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:40

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:40

Condition	HEART MURMUR
Start date (dd MMM yyyy)	UN UNK 1988
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:40

Condition	ACE INHIBITOR ALLERGY
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:40

Condition	ROTATOR CUFF SURGERY
Start date (dd MMM yyyy)	20 FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	20 FEB 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	FEB 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:40

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:40

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:40

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

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:40

Condition	TORN TENDON
Start date (dd MMM yyyy)	20 FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	20 FEB 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	FEB 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:40

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	9 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	13:55 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 13:55
Height (<i>xxx.x</i>)	73 in
Weight (<i>xxx.x</i>)	228.7 lb
BMI (<i>xxx.x</i>)	30.23642 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	96.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	106 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify REALTOR

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	True
Specify	RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:40

What was the date of randomization? (dd MMM yyyy) 16 OCT 2020

What was the participant's randomization number? 147186

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:40

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:40

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 11:50
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:40

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	13:30 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 13:30
Temperature (xxx.x)	98.0 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:40

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:40

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	16 OCT 2020
What was the treatment time? (00:00-23:59)	13:00 (24 HR)
Treatment Date and Time (derived)	16 OCT 2020 13:00
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 09:32:40

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	16 OCT 2020
Collection time (<i>00:00-23:59</i>)	12:30 (24 HR)
Collection date and time (derived)	16 OCT 2020 12:30

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:32:40

Collection date (<i>dd MMM yyyy</i>)			16 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	12:35	16 OCT 2020 12:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:32:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

16 OCT 2020 13:28

PC Open Date & Time

16 OCT 2020 13:20

PC Close Date & Time

16 OCT 2020 15:50

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp	17 OCT 2020 01:02
PC Open Date & Time	16 OCT 2020 16:45
PC Close Date & Time	17 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

17 OCT 2020 17:18

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp 18 OCT 2020 19:10

PC Open Date & Time 18 OCT 2020 12:00

PC Close Date & Time 19 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 17:51

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 21:10

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 20:06

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 OCT 2020 20:55

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

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

16 OCT 2020 13:29

PC Open Date & Time

16 OCT 2020 13:20

PC Close Date & Time

16 OCT 2020 15:50

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

Please record - **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

17 OCT 2020 01:03

PC Open Date & Time

16 OCT 2020 16:45

PC Close Date & Time

17 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 17:19

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 19:11

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 17:52

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 21:11

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 OCT 2020 20:06

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 OCT 2020 20:56

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

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

No ☒

Yes ☐

PC Time stamp	16 OCT 2020 13:30
PC Open Date & Time	16 OCT 2020 13:20
PC Close Date & Time	16 OCT 2020 15:50

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

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

No ☒

Yes ☐

PC Time stamp	17 OCT 2020 01:04
PC Open Date & Time	16 OCT 2020 16:45
PC Close Date & Time	17 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:40

Yes ☐	
PC Time stamp	17 OCT 2020 17:21
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:40

Yes ☐	
PC Time stamp	18 OCT 2020 19:13
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:40

Yes ☐	
PC Time stamp	19 OCT 2020 17:52
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:40

Yes ☐	
PC Time stamp	20 OCT 2020 21:11
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:40

Yes ☐	
PC Time stamp	21 OCT 2020 20:07
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:40

Yes ☐	
PC Time stamp	22 OCT 2020 20:57
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3482284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:40

Was Contact Attempted?

Yes ☒

No ☐

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

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482284

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482284

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3482284

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3482284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

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 _____

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:40

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

US3482284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:40

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

US3482284

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:40

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3482284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:40

Was study treatment given? Yes ☐
No ☐

If No, reason not given

Participant declined due to ☐
Adverse Event ☐
Physician withheld dose due to ☐
Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by ☐
Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? _____

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? _____

US3482284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:40

Was the sample collected?	Yes ☐
	No ☐

Collection date (<i>dd MMM yyyy</i>)	
Collection time (<i>00:00-23:59</i>)	
Collection date and time (derived)	

US3482284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:32:40

Collection date (dd MMM yyyy)			
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1			
Nasopharyngeal Swab 2			

US3482284

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:40

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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30 DEC 2021 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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06 JAN 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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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09 JAN 2022 00:01

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13 JAN 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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27 JAN 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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17 FEB 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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24 FEB 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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03 MAR 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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16 JUN 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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23 JUN 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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07 JUL 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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14 JUL 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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21 JUL 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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28 JUL 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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04 AUG 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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25 AUG 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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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28 AUG 2022 00:01

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01 SEP 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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

Date and time of submission

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04 SEP 2022 00:01

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08 SEP 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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15 SEP 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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22 SEP 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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29 SEP 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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06 OCT 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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13 OCT 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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20 OCT 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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27 OCT 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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03 NOV 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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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06 NOV 2022 00:01

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10 NOV 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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17 NOV 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

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24 NOV 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

01 DEC 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

08 DEC 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

15 DEC 2022 23:59

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

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

[Patient Cloud Close Date & Time](#)

22 DEC 2022 23:59

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:32:40

Date of Contact	12 NOV 2020
Time of Contact	16:00
Date and Time of Contact (derived)	12 NOV 2020 16:00
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 ☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.6 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)	290 of 2337	

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	28 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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)	294 of 2337	

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

	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	☒

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	29 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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)	298 of 2337	

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

	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	☒

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	30 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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)	302 of 2337	

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

	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	☒

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	31 OCT 2020	
Assessment Not Done	True	
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)	306 of 2337	

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	01 NOV 2020	
Assessment Not Done	True	
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)	310 of 2337	

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	02 NOV 2020	
Assessment Not Done	True	
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)	314 of 2337	

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	03 NOV 2020	
Assessment Not Done	True	
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)	318 of 2337	

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	04 NOV 2020	
Assessment Not Done	True	
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)	322 of 2337	

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	05 NOV 2020	
Assessment Not Done	True	
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)	326 of 2337	

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

	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	☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	6 NOV 2020	
Assessment Not Done	True	
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)	330 of 2337	

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	7 NOV 2020	
Assessment Not Done	True	
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)	334 of 2337	

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	8 NOV 2020	
Assessment Not Done	True	
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)	338 of 2337	

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

	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	☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	9 NOV 2020	
Assessment Not Done	True	
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)	342 of 2337	

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	10 NOV 2020	
Assessment Not Done	True	
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)	346 of 2337	

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

	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	☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	11 NOV 2020	
Assessment Not Done	True	
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)	350 of 2337	

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

	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	☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

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	☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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)	354 of 2337	

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

	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	☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

	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	☒

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[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	☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	96.8 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)	358 of 2337	

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

	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	☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

	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	☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

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	☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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)	362 of 2337	

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

	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	☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

	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	☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

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	☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.6 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)	366 of 2337	

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

	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	☐

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:40

Date of Visit	13 NOV 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	13 NOV 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)	0

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:32:40

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:32:40

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	15 NOV 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3482284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	13 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	10:34 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 10:34
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	97.6 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	89 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	26 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	98 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3482284

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 NOV 2020

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

US3482284

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:32:40

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 NOV 2020

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

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	SICKD28

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

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

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:40

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3482284

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:32:40

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3482284

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:32:40

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

AEID	USA-US106-2020-MRNA-1273-P30 1000002
Adverse event	MYOCARDIAL INFARCTION
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	28 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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	29 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	31 OCT 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
Number of Days in ICU	1

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

Persistent or significant disability or incapacity	True
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☒ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	SHORTNESS OF BREATH & IMPAIRED CARDIAC FUNCTION (CHF)
Narrative	

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

SUBJECT WITH CHEST PAIN
BEGINNING 28OCT2020.
INITIALLY THOUGHT IT WAS
INDIGESTION DUE TO DINNER
FROM PREVIOUS NIGHT. IT
PERSISTED TO 29OCT2020, AND
PT STARTED HAVING
DIZZINESS AND SHORTNESS OF
BREATH WITH CLIMBING A
LADDER FOR WORK, SO
SUBJECT WENT TO ED. EKG
REVEALED ST ELEVATION MI
AND LABS SHOWED ELEVATED
TROPONIN (MAX 45.5). WAS
TREATED WITH NTG, ASAS,
AND HEPARIN IV. SUBJECT
UNDERWENT EMERGENT
CARDIAC CATHETERIZATION
WITH UNSUCCESSFUL
THROMBECTOMY &
ANGIOPLASTY TO TOTALLY
OCCLUDED MID RCA. HE WAS
TRANSFERRED TO ICU FOR
ONGOING CARE. WAS TREATED
WITH INTEGRILIN DRIP,
MORPHINE FOR PAIN, AND
CONTINUED BASELINE
STATINS, BETA BLOCKER, AND
AMLODIPINE. WAS NOTED TO
HAVE RENAL IMPAIRMENT ON
ADMISSION LABS. COVID PCR
WAS NEGATIVE. PARTICIPANT
IMPROVED DURING
ADMISSION AND WAS D/C'D TO
RETURN TO ATLANTA FOR F/U
WITH REGULAR
CARDIOLOGIST FOR FURTHER
MANAGEMENT.

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

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

AEID	USA-US106-2020-MRNA-1273-P30 1000002
Adverse event	SHORTNESS OF BREATH
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	28 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)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	5 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	7 NOV 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
Number of Days in ICU	1

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

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

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

PARTICIPANT WITH SOB SINCE SYMPTOM ONSET PRIOR TO DIAGNOSED MYOCARDIAL INFARCTION 31 OCT. WAS SEEN AT PCP FOR REGULAR FOLLOW UP 5 NOV, AND HAD SOB THAT MD DEEMED SIGNIFICANT ENOUGH TO REFER PT TO ER FOR ECHOCARDIOGRAM AND EVAL. PT WAS SEEN AT ER, ADMITTED TO HOSPITAL, TRANSFERRED TO ICU PER HIS REPORT. CARDIAC PROCEDURE/SURGERY OF UNKNOWN TYPE WAS OFFERED TO PARTICIPANT WHO DECLINED, WANTING TO CONSULT HIS OWN CARDIOLOGIST. THEREAFTER PARTICIPANT WAS DISCHARGED/LEFT AMA AND IS AWAITING FURTHER OUTPATIENT IMAGING AND EVALUATION THIS WEEK TO DECIDE NEXT STEPS. WE ARE AWAITING FULL HOSPITAL D/C RECORDS AT THIS TIME. PT CURRENTLY NOTES SOB AT REST, WITH INCREASED TALKING. HAD 3 NEGATIVE COVID TESTS SINCE LAST IN CLINIC AND WILL HAVE AN ILLNESS VISIT HERE 13 NOV 2020.

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

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

AEID	USA-US106-2020-MRNA-1273-P30 1000002
Adverse event	ACUTE ON CHRONIC SYSTOLIC HEART FAILURE
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)	5 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	True
Hospital Admission Date (dd MMM yyyy)	5 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	7 NOV 2020
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
Number of Days in ICU	1
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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

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

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

PARTICIPANT WITH SOB SINCE SYMPTOM ONSET PRIOR TO DIAGNOSED MYOCARDIAL INFARCTION 31 OCT. WAS SEEN AT PCP FOR REGULAR FOLLOW UP 5 NOV, AND HAD SOB THAT MD DEEMED SIGNIFICANT ENOUGH TO REFER PT TO ER FOR ECHOCARDIOGRAM AND EVAL. PT WAS SEEN AT ER, ADMITTED TO HOSPITAL, TRANSFERRED TO ICU PER HIS REPORT. CARDIAC PROCEDURE/SURGERY OF UNKNOWN TYPE WAS OFFERED TO PARTICIPANT WHO DECLINED, WANTING TO CONSULT HIS OWN CARDIOLOGIST. THEREAFTER PARTICIPANT WAS DISCHARGED/LEFT AMA AND IS AWAITING FURTHER OUTPATIENT IMAGING AND EVALUATION THIS WEEK TO DECIDE NEXT STEPS. WE ARE STILL AWAITING FULL HOSPITAL D/C RECORDS AT THIS TIME. NO REPORT OF CHF IN PMHX PRIOR TO HEART ATTACK IN LATE OCTOBER.

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

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

AEID	
Adverse event	CHEST PAIN
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	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	True
Hospital Admission Date (dd MMM yyyy)	18 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

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	

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

SUBJECT BEGAN HAVING
CHEST PAIN AFTER SAFETY
CALL WAS COMPLETED ON
16NOV2020 AND SOUGHT
MEDICAL ATTENTION IN ED.
TEAM WAS NOTIFIED ON
19NOV2020 OF ADMISSION TO
HOSPITAL FOR EVALUATION
OF "ARRHYTHMIA" AND
"FLUTTER" PER SUBJECT
DESCRIPTION. MEDICAL
RECORDS PENDING.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:32:40

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

Yes ☒

No ☐

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

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	HYPERLIPIDEMIA
Dose per administration	20
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2018
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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

Name of Medication	METOPROLOL
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

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

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

Name of Medication	LOSARTAN
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	50
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

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

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

Name of Medication	ASPIRIN
Prophylaxis	Yes ☒ No ☐
Indication	HEART HEALTH
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 ☐

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
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	☒

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

Name of Medication	TRIAMETERENE HCTZ
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	37.5/25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	5 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	☒

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

Name of Medication	AMLODIPINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		5 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	☒

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

Name of Medication	DESCOVY
Prophylaxis	Yes ☒ No ☐
Indication	HIV PROPHYLAXIS
Dose per administration	25
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
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	☒

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

Name of Medication	ZOLPIDEM
Prophylaxis	Yes ☐ No ☒
Indication	INSOMNIA
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2019
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	☐

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

Name of Medication	RED VOLT PRE-WORKOUT SUPPLEMENT
Prophylaxis	Yes ☐ No ☒
Indication	WEIGHT LOSS
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☒ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

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

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

Name of Medication	IMMUNE SUPPORT VITAMIN
Prophylaxis	Yes ☒ No ☐
Indication	HEALTH MAINTENANCE
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

	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 MAR 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	☒

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

Name of Medication	HEPARIN
Prophylaxis	Yes ☐ No ☒
Indication	AE # 1 (MYOCARDIAL INFARCTION)
Dose per administration	5000
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNITS
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

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

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

Name of Medication	NITROGLYCERINE
Prophylaxis	Yes ☐ No ☒
Indication	MYOCARDIAL INFARCTION (AE#1)
Dose per administration	50
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	MG/250 ML
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 ☐

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☒
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		20 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 ☐	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ☒
Indication	AE#1 (MYOCARDIAL INFARCTION)
Dose per administration	325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

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

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

Name of Medication	CLOPIDOGREL
Prophylaxis	Yes ☐ No ☒
Indication	AE#1 (MYOCARDIAL INFARCTION)
Dose per administration	75
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 ☐

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	30 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

Name of Medication	SEROQUEL
Prophylaxis	Yes ☐ No ☒
Indication	INSOMNIA
Dose per administration	200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

	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)		30 OCT 2020
Was this medication taken for solicited event?		Yes ☐
		No ☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☒

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

Name of Medication	SEROQUEL
Prophylaxis	Yes ☐ No ☒
Indication	INSOMNIA
Dose per administration	100
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

	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)		31 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	HYPERLIPIDEMIA
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

	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)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:32:40

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:32:40

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
29 OCT 2020	CARDIAC CATHETERIZATION WITH ANGIOGRAPHY AND PERCUTANEOUS CORONARY INTERVENTION	Adverse Event	

US3482284

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:32:40

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3482284

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:32:40

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 ☐

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

SAEID	USA-US106-2020-MRNA-1273-P301000002
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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:32:40

SAEID	USA-US106-2020-MRNA-1273-P301000002
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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	02/NOV/2020 16:18
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

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:32:40

SAEID	USA-US106-2020-MRNA-1273-P301000002
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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	09/NOV/2020 19:50
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

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:32:40

SAEID	USA-US106-2020-MRNA-1273-P301000002
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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	11/NOV/2020 13:41
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

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:32:40

SAEID	USA-US106-2020-MRNA-1273-P301000002
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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/NOV/2020 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.	True

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:32:40

SAEID	USA-US106-2020-MRNA-1273-P301000002
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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	17/NOV/2020 14:34
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

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:32:40

SAEID	USA-US106-2020-MRNA-1273-P301000002
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	EASTON
Investigator's Last Name	BESHEARS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	18/NOV/2020 21:05
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

US3482284 (Prod: Hope Clinic of The Emory Vaccine Center)

US3482284

Form: Participant Creation

Generated On: 26 Nov 2020 09:32:40

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3482284'	RWS_ENDPOINT ENDPOINT (b) (4) 	09 Oct 2020 17:52:46

US3482284

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:07:35

US3482284

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '09 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	09 Oct 2020 17:52:47

US3482284

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Oct 2020 19:07:35

US3482284

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	09 Oct 2020 19:07:35

US3482284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered (b) (6) 1958'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	09 Oct 2020 17:52:48

US3482284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:40

[Age](#)

Audit	User	Time (GMT)
User entered '62'	(b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:40

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:40

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '62'	System	09 Oct 2020 19:14:41

US3482284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:40

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	(b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:40

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:40

[White](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:40

[Black](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:40

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:40

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:40

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:40

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:40

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:40

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:40

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:13:57

US3482284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 19:14:41

US3482284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Oct 2020'	System	09 Oct 2020 19:14:41

US3482284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '2020'	System	09 Oct 2020 19:14:41

US3482284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:40

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 4 (4)' reason for change:	(b) (4), (b) (6)	19 Oct 2020 21:20:16
Data Entry Error		
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	09 Oct 2020 19:14:41

US3482284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:14:41

US3482284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:14:41

US3482284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:40

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:14:41

US3482284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:40

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 19:14:41

US3482284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:40

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	09 Oct 2020 17:52:47

US3482284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:40

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 19:14:57

US3482284

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:14:57

US3482284

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:32:40

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:08:01

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:36:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:36:54
Data point term sent to Coder	System	16 Oct 2020 20:17:22
User entered 'Hypertension'	(b) (4), (b) (6) (b) (4)	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	(b) (4), (b) (6)	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '2014'	System	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 20:16:45

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Heart murmur - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 09:38:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 09:38:04
Data point term sent to Coder	System	16 Oct 2020 20:18:23
User entered 'Heart Murmur'	(b) (4), (b) (6)	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'un UNK 1988'	(b) (4), (b) (6)	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Jan 1988'	System	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '1988'	System	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 20:17:27

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:38:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:38:54
Data point term sent to Coder	System	16 Oct 2020 20:19:29
User entered 'ACE Inhibitor Allergy'	(b) (4), (b) (6)	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2009'	(b) (4), (b) (6)	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '2009'	System	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 20:19:02

US3482284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:40

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 12:52:11
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' answered with 'Updated medical history to reflect that surgery was completed because of torn tendon' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:57:34
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 09:38:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:39:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:39:37
Data point term sent to Coder	System	16 Oct 2020 20:20:32
User entered 'Rotator Cuff Surgery'	(b) (4), (b) (6)	16 Oct 2020 20:19:48

US3482284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '20 Feb 2020'	(b) (4), (b) (6)	16 Oct 2020 20:19:48

US3482284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:19:48

US3482284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 20:19:48

US3482284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '20 Feb 2020'	(b) (4), (b) (6)	16 Oct 2020 20:19:48

US3482284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:19:48

US3482284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Feb 2020'	System	16 Oct 2020 20:19:48

US3482284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '2020'	System	16 Oct 2020 20:19:48

US3482284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Feb 2020'	System	16 Oct 2020 20:19:48

US3482284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '2020'	System	16 Oct 2020 20:19:48

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:39:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:39:37
Data point term sent to Coder	System	16 Oct 2020 20:20:33
User entered 'Insomnia'	(b) (4), (b) (6)	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	(b) (4), (b) (6)	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '2019'	System	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 20:20:14

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:40:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:40:09
Data point term sent to Coder	System	16 Oct 2020 20:21:35
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	(b) (4), (b) (6)	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '2018'	System	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 20:20:49

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Heart rate and pulse investigations, PT: Heart rate irregular, LLT: Heart rate irregular - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:40:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:40:10
Data point term sent to Coder	System	16 Oct 2020 20:21:35
User entered 'Irregular Heart Rhythm'	(b) (4), (b) (6)	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'un UNK 1995'	(b) (4), (b) (6)	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '1995'	System	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 20:21:21

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Tendon rupture, LLT: Tendon rupture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:57:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:57:27
Data point term sent to Coder	System	26 Oct 2020 19:56:17
User entered 'Torn Tendon'	(b) (4), (b) (6) (b) (4), (b) (6)	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '20 Feb 2020'	(b) (4), (b) (6)	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '20 Feb 2020'	(b) (4), (b) (6)	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Feb 2020'	System	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '2020'	System	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Feb 2020'	System	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '2020'	System	26 Oct 2020 19:56:15

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease stage 3 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:21:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:21:01
Data point term sent to Coder	System	17 Nov 2020 21:16:17
User entered 'CHRONIC KIDNEY DISEASE stage IIIa'	(b) (4), (b) (6) (b) (4)	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 21:16:08

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '13:55'	(b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '9 Oct 2020 13:55'	System	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '73' in	(b) (4), (b) (6)	09 Oct 2020 19:17:07
DataPoint set to visible.	System	09 Oct 2020 19:14:57

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '228.7' lb	(b) (4), (b) (6)	09 Oct 2020 19:17:07
DataPoint set to visible.	System	09 Oct 2020 19:14:57

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '30.23642'	System	09 Oct 2020 19:17:07
DataPoint set to visible.	System	09 Oct 2020 19:14:57

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	09 Oct 2020 19:17:07
DataPoint set to visible.	System	09 Oct 2020 19:14:57

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	09 Oct 2020 19:18:03
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	System	09 Oct 2020 19:18:03
answered by data change (Site from System).		
User entered '96.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 19:18:03
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	09 Oct 2020 19:17:07
User entered '96.7' F	(b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '83'	(b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '148'	(b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 10:41:58
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 19:17:32
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		09 Oct 2020 19:17:07
User entered '106'	(b) (4), (b) (6)	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 19:17:07

US3482284

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 17:49:33
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:08:13

US3482284

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 17:49:33
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:08:13

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

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)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

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)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

[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)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

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)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

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)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

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)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

[Specify](#)

Audit	User	Time (GMT)
User entered 'Realtor'	(b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

[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)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

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)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

[Other](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 16:07:50
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:40

[Specify](#)

Audit	User	Time (GMT)
User closed query 'Other specified is provided for Location and Living Circumstances Risk, but OTHER is not selected for Location and Living Circumstances Risk. Please reconcile.' (Site from System).	System	16 Oct 2020 16:07:50
User opened query 'Other specified is provided for Location and Living Circumstances Risk, but OTHER is not selected for Location and Living Circumstances Risk. Please reconcile.' (Site from System).	System	16 Oct 2020 16:07:41
User entered 'Resident in a community with ongoing person to person transmission'	(b) (4), (b) (6)	16 Oct 2020 16:07:41

US3482284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 15:53:57

US3482284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 15:53:57

US3482284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Oct 2020 15:53:57

US3482284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	16 Oct 2020 15:53:57

US3482284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '16 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	16 Oct 2020 16:43:28

US3482284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '147186'	RWS_ENDPOINT ENDPOINT (b) (4) 	16 Oct 2020 16:43:28

US3482284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:40

[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) 	16 Oct 2020 16:43:28

US3482284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:53:30

US3482284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:53:30

US3482284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:53:30

US3482284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:40

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:53:30

US3482284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:40

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:53:30

US3482284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:53:30
DataPoint set to visible.	System	09 Oct 2020 19:14:41

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:40

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:40

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:40

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:40

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '11:50'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:50'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '90'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '138'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '85'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:40

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:40

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '13:30'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 13:30'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '90'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '125'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80'	(b) (4), (b) (6)	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Oct 2020 20:13:07

US3482284

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 17:49:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:53:41

US3482284

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 17:49:59
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 16:53:41

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:40

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:40

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)	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '13:00'	(b) (4), (b) (6)	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 13:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	16 Oct 2020 17:06:58

US3482284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:54:01

US3482284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 16:54:01

US3482284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '12:30'	(b) (4), (b) (6)	16 Oct 2020 16:54:01

US3482284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:30'	System	16 Oct 2020 16:54:01

US3482284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:32:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 16:54:18

US3482284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Oct 2020 16:54:18

US3482284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:54:18

US3482284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '12:35'	(b) (4), (b) (6)	16 Oct 2020 16:54:18

US3482284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:35'	System	16 Oct 2020 16:54:18

US3482284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Oct 2020 16:54:18

US3482284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 16:54:18

US3482284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 16:54:18

US3482284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:54:18

US3482284

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 16:54:27

US3482284

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:32:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 16:54:27

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:27:45', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '184cc023-f3ac-4dcc-a185-1725ec03b523'	System	16 Oct 2020 17:28:38
User entered 'Yes (Y)'	System	16 Oct 2020 17:28:38

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:28:06', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '184cc023-f3ac-4dcc-a185-1725ec03b523'	System	16 Oct 2020 17:28:38
User entered '98.0'	System	16 Oct 2020 17:28:38

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:28:16', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '184cc023-f3ac-4dcc-a185-1725ec03b523'	System	16 Oct 2020 17:28:38
User entered 'No (N)'	System	16 Oct 2020 17:28:38

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:28:32', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '184cc023-f3ac-4dcc-a185-1725ec03b523'	System	16 Oct 2020 17:28:38
User entered '16 Oct 2020 13:28'	System	16 Oct 2020 17:28:38

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 13:20'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 15:50'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:01:48', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1b42afa6-27c0-403c-adc0-9502ae11d4ff' User entered 'Yes (Y)'	System	17 Oct 2020 05:02:38
	System	17 Oct 2020 05:02:38

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:02:22', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1b42afa6-27c0-403c-adc0-9502ae11d4ff' User entered '97.6'	System	17 Oct 2020 05:02:38

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:02:30', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1b42afa6-27c0-403c-adc0-9502ae11d4ff'	System	17 Oct 2020 05:02:38
User entered 'No (N)'	System	17 Oct 2020 05:02:38

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:02:35', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1b42afa6-27c0-403c-adc0-9502ae11d4ff' User entered '17 Oct 2020 01:02'	System	17 Oct 2020 05:02:38
	System	17 Oct 2020 05:02:38

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 16:45'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 2'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:18:07', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '492a374b-b9b4-47d2-bffd-235091646678'	System	17 Oct 2020 21:18:58
User entered 'Yes (Y)'	System	17 Oct 2020 21:18:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:18:25', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '492a374b-b9b4-47d2-bffd-235091646678' User entered '97.8'	System	17 Oct 2020 21:18:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:18:32', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '492a374b-b9b4-47d2-bffd-235091646678'	System	17 Oct 2020 21:18:58
User entered 'No (N)'	System	17 Oct 2020 21:18:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:18:55', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '492a374b-b9b4-47d2-bffd-235091646678'	System	17 Oct 2020 21:18:58
User entered '17 Oct 2020 17:18'	System	17 Oct 2020 21:18:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 3'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:09:57', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '772aa036-a45b-4127-a9f9-a9fd8ae36465'	System	18 Oct 2020 23:10:48
User entered 'Yes (Y)'	System	18 Oct 2020 23:10:48

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:10:32', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '772aa036-a45b-4127-a9f9-a9fd8ae36465' User entered '97.6'	System	18 Oct 2020 23:10:48

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:10:39', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '772aa036-a45b-4127-a9f9-a9fd8ae36465' User entered 'No (N)'	System	18 Oct 2020 23:10:48

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:10:47', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '772aa036-a45b-4127-a9f9-a9fd8ae36465' User entered '18 Oct 2020 19:10'	System	18 Oct 2020 23:10:48
	System	18 Oct 2020 23:10:48

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 4'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:51:09', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1d6006dc-332b-413c-aa1c-606afc8765c8'	System	19 Oct 2020 21:51:34
User entered 'Yes (Y)'	System	19 Oct 2020 21:51:34

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:51:22', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1d6006dc-332b-413c-aa1c-606afc8765c8'	System	19 Oct 2020 21:51:34
User entered '97.4'	System	19 Oct 2020 21:51:34

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:51:27', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1d6006dc-332b-413c-aa1c-606afc8765c8'	System	19 Oct 2020 21:51:34
User entered 'No (N)'	System	19 Oct 2020 21:51:34

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:51:31', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1d6006dc-332b-413c-aa1c-606afc8765c8' User entered '19 Oct 2020 17:51'	System	19 Oct 2020 21:51:34
	System	19 Oct 2020 21:51:34

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 5'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:10:29', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'c8f069a2-d393-4725-a76f-4a287f0d5806'	System	21 Oct 2020 01:10:53
User entered 'Yes (Y)'	System	21 Oct 2020 01:10:53

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:10:37', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'c8f069a2-d393-4725-a76f-4a287f0d5806'	System	21 Oct 2020 01:10:53
User entered '97.7'	System	21 Oct 2020 01:10:53

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:10:42', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'c8f069a2-d393-4725-a76f-4a287f0d5806'	System	21 Oct 2020 01:10:53
User entered 'No (N)'	System	21 Oct 2020 01:10:53

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:10:46', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'c8f069a2-d393-4725-a76f-4a287f0d5806'	System	21 Oct 2020 01:10:53
User entered '20 Oct 2020 21:10'	System	21 Oct 2020 01:10:53

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 6'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:05:48', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd0076913-8ebd-434e-ae3b-5f06e948ceec'	System	22 Oct 2020 00:06:11
User entered 'Yes (Y)'	System	22 Oct 2020 00:06:11

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:05:56', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd0076913-8ebd-434e-ae3b-5f06e948ceec'	System	22 Oct 2020 00:06:11
User entered '97.9'	System	22 Oct 2020 00:06:11

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:06', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd0076913-8ebd-434e-ae3b-5f06e948ceec'	System	22 Oct 2020 00:06:11
User entered 'No (N)'	System	22 Oct 2020 00:06:11

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:09', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd0076913-8ebd-434e-ae3b-5f06e948ceec'	System	22 Oct 2020 00:06:11
User entered '21 Oct 2020 20:06'	System	22 Oct 2020 00:06:11

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 7'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:55:29', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'ffcaa6a4-98ae-4323-8ea2-854285c5aeec'	System	23 Oct 2020 00:55:52
User entered 'Yes (Y)'	System	23 Oct 2020 00:55:52

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:55:39', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'ffcaa6a4-98ae-4323-8ea2-854285c5aeec'	System	23 Oct 2020 00:55:52
User entered '97.3'	System	23 Oct 2020 00:55:52

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:55:45', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'ffcaa6a4-98ae-4323-8ea2-854285c5aeec'	System	23 Oct 2020 00:55:52
User entered 'No (N)'	System	23 Oct 2020 00:55:52

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:55:50', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'ffcaa6a4-98ae-4323-8ea2-854285c5aeec'	System	23 Oct 2020 00:55:52
User entered '22 Oct 2020 20:55'	System	23 Oct 2020 00:55:52

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

[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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:28:56', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd24b50bf-b63b-476e-b2f0-05c8f4ef5b23'	System	16 Oct 2020 17:29:51
User entered 'None (1)'	System	16 Oct 2020 17:29:51

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:29:03', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd24b50bf-b63b-476e-b2f0-05c8f4ef5b23'	System	16 Oct 2020 17:29:51
User entered 'No (N)'	System	16 Oct 2020 17:29:51

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:29:10', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd24b50bf-b63b-476e-b2f0-05c8f4ef5b23'	System	16 Oct 2020 17:29:51
User entered 'No (N)'	System	16 Oct 2020 17:29:51

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:29:33', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd24b50bf-b63b-476e-b2f0-05c8f4ef5b23'	System	16 Oct 2020 17:29:51
User entered 'None (1)'	System	16 Oct 2020 17:29:51

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:29:45', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd24b50bf-b63b-476e-b2f0-05c8f4ef5b23'	System	16 Oct 2020 17:29:51
User entered '16 Oct 2020 13:29'	System	16 Oct 2020 17:29:51

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 13:20'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 15:50'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:02:48', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'e65d8c9a-43e6-4285-81bd-2143cde9d1d4'	System	17 Oct 2020 05:03:19
User entered 'None (1)'	System	17 Oct 2020 05:03:19

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:02:53', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'e65d8c9a-43e6-4285-81bd-2143cde9d1d4'	System	17 Oct 2020 05:03:19
User entered 'No (N)'	System	17 Oct 2020 05:03:19

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:03:03', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'e65d8c9a-43e6-4285-81bd-2143cde9d1d4'	System	17 Oct 2020 05:03:19
User entered 'No (N)'	System	17 Oct 2020 05:03:19

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:03:08', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'e65d8c9a-43e6-4285-81bd-2143cde9d1d4'	System	17 Oct 2020 05:03:19
User entered 'None (1)'	System	17 Oct 2020 05:03:19

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:03:16', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'e65d8c9a-43e6-4285-81bd-2143cde9d1d4'	System	17 Oct 2020 05:03:19
User entered '17 Oct 2020 01:03'	System	17 Oct 2020 05:03:19

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 16:45'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 2'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:19:06', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '25be8d7d-8fcd-4877-96f7-5921d87d9acb'	System	17 Oct 2020 21:19:54
User entered 'None (1)'	System	17 Oct 2020 21:19:54

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:19:10', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '25be8d7d-8fcd-4877-96f7-5921d87d9acb'	System	17 Oct 2020 21:19:54
User entered 'No (N)'	System	17 Oct 2020 21:19:54

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:19:15', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '25be8d7d-8fcd-4877-96f7-5921d87d9acb'	System	17 Oct 2020 21:19:54
User entered 'No (N)'	System	17 Oct 2020 21:19:54

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:19:42', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '25be8d7d-8fcd-4877-96f7-5921d87d9acb'	System	17 Oct 2020 21:19:54
User entered 'None (1)'	System	17 Oct 2020 21:19:54

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:19:52', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '25be8d7d-8fcd-4877-96f7-5921d87d9acb' User entered '17 Oct 2020 17:19'	System	17 Oct 2020 21:19:54
	System	17 Oct 2020 21:19:54

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 3'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:10:56', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1c6ebc16-b86b-4aa9-94d1-4a62ad49ce98'	System	18 Oct 2020 23:11:35
User entered 'None (1)'	System	18 Oct 2020 23:11:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:11:01', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1c6ebc16-b86b-4aa9-94d1-4a62ad49ce98'	System	18 Oct 2020 23:11:35
User entered 'No (N)'	System	18 Oct 2020 23:11:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:11:08', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1c6ebc16-b86b-4aa9-94d1-4a62ad49ce98'	System	18 Oct 2020 23:11:35
User entered 'No (N)'	System	18 Oct 2020 23:11:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:11:27', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1c6ebc16-b86b-4aa9-94d1-4a62ad49ce98'	System	18 Oct 2020 23:11:35
User entered 'None (1)'	System	18 Oct 2020 23:11:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:11:31', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '1c6ebc16-b86b-4aa9-94d1-4a62ad49ce98'	System	18 Oct 2020 23:11:35
User entered '18 Oct 2020 19:11'	System	18 Oct 2020 23:11:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 4'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:51:39', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '96429364-b4d0-4d28-b31d-44d7d33703fe' User entered 'None (1)'	System	19 Oct 2020 21:52:11

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:51:54', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '96429364-b4d0-4d28-b31d-44d7d33703fe'	System	19 Oct 2020 21:52:11
User entered 'No (N)'	System	19 Oct 2020 21:52:11

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:51:58', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '96429364-b4d0-4d28-b31d-44d7d33703fe'	System	19 Oct 2020 21:52:11
User entered 'No (N)'	System	19 Oct 2020 21:52:11

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:02', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '96429364-b4d0-4d28-b31d-44d7d33703fe'	System	19 Oct 2020 21:52:11
User entered 'None (1)'	System	19 Oct 2020 21:52:11

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:07', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '96429364-b4d0-4d28-b31d-44d7d33703fe' User entered '19 Oct 2020 17:52'	System	19 Oct 2020 21:52:11

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 5'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:10:52', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'c0d3e374-d522-462a-a07a-97b50c4e65e8' User entered 'None (1)'	System	21 Oct 2020 01:11:21
	System	21 Oct 2020 01:11:21

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:10:57', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'c0d3e374-d522-462a-a07a-97b50c4e65e8' User entered 'No (N)'	System	21 Oct 2020 01:11:21
	System	21 Oct 2020 01:11:21

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:02', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'c0d3e374-d522-462a-a07a-97b50c4e65e8'	System	21 Oct 2020 01:11:21
User entered 'No (N)'	System	21 Oct 2020 01:11:21

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:08', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'c0d3e374-d522-462a-a07a-97b50c4e65e8'	System	21 Oct 2020 01:11:21
User entered 'None (1)'	System	21 Oct 2020 01:11:21

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:11', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'c0d3e374-d522-462a-a07a-97b50c4e65e8' User entered '20 Oct 2020 21:11'	System	21 Oct 2020 01:11:21
	System	21 Oct 2020 01:11:21

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 6'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:14', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '376b7191-baa9-4b16-a04e-d2a30d2430c3'	System	22 Oct 2020 00:06:42
User entered 'None (1)'	System	22 Oct 2020 00:06:42

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:17', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '376b7191-baa9-4b16-a04e-d2a30d2430c3'	System	22 Oct 2020 00:06:42
User entered 'No (N)'	System	22 Oct 2020 00:06:42

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:28', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '376b7191-baa9-4b16-a04e-d2a30d2430c3'	System	22 Oct 2020 00:06:42
User entered 'No (N)'	System	22 Oct 2020 00:06:42

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:37', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '376b7191-baa9-4b16-a04e-d2a30d2430c3'	System	22 Oct 2020 00:06:42
User entered 'None (1)'	System	22 Oct 2020 00:06:42

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:40', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '376b7191-baa9-4b16-a04e-d2a30d2430c3'	System	22 Oct 2020 00:06:42
User entered '21 Oct 2020 20:06'	System	22 Oct 2020 00:06:42

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 7'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:40

[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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:55:58', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '4e8f3da6-c6e9-4d53-b8ba-776070167efb'	System	23 Oct 2020 00:56:35
User entered 'None (1)'	System	23 Oct 2020 00:56:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:10', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '4e8f3da6-c6e9-4d53-b8ba-776070167efb'	System	23 Oct 2020 00:56:35
User entered 'No (N)'	System	23 Oct 2020 00:56:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:18', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '4e8f3da6-c6e9-4d53-b8ba-776070167efb' User entered 'No (N)'	System	23 Oct 2020 00:56:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:30', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '4e8f3da6-c6e9-4d53-b8ba-776070167efb'	System	23 Oct 2020 00:56:35
User entered 'None (1)'	System	23 Oct 2020 00:56:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:33', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '4e8f3da6-c6e9-4d53-b8ba-776070167efb'	System	23 Oct 2020 00:56:35
User entered '22 Oct 2020 20:56'	System	23 Oct 2020 00:56:35

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:30:00', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '63677027-8c81-471d-8ba2-e887e5398492'	System	16 Oct 2020 17:31:01
User entered 'None (0)'	System	16 Oct 2020 17:31:01

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:30:08', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '63677027-8c81-471d-8ba2-e887e5398492'	System	16 Oct 2020 17:31:01
User entered 'None (0)'	System	16 Oct 2020 17:31:01

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:30:17', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '63677027-8c81-471d-8ba2-e887e5398492'	System	16 Oct 2020 17:31:01
User entered 'None (0)'	System	16 Oct 2020 17:31:01

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:30:24', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '63677027-8c81-471d-8ba2-e887e5398492'	System	16 Oct 2020 17:31:01
User entered 'None (0)'	System	16 Oct 2020 17:31:01

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:30:35', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '63677027-8c81-471d-8ba2-e887e5398492'	System	16 Oct 2020 17:31:01
User entered 'None (0)'	System	16 Oct 2020 17:31:01

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:30:39', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '63677027-8c81-471d-8ba2-e887e5398492'	System	16 Oct 2020 17:31:01
User entered 'None (0)'	System	16 Oct 2020 17:31:01

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:30:49', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '63677027-8c81-471d-8ba2-e887e5398492'	System	16 Oct 2020 17:31:01
User entered 'No (N)'	System	16 Oct 2020 17:31:01

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-16T13:30:57', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '63677027-8c81-471d-8ba2-e887e5398492'	System	16 Oct 2020 17:31:01
User entered '16 Oct 2020 13:30'	System	16 Oct 2020 17:31:01

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 13:20'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 15:50'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:03:22', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7e04d044-e34e-43e0-be6c-19def3c9870f'	System	17 Oct 2020 05:04:09
User entered 'None (0)'	System	17 Oct 2020 05:04:09

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:03:26', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7e04d044-e34e-43e0-be6c-19def3c9870f'	System	17 Oct 2020 05:04:09
User entered 'None (0)'	System	17 Oct 2020 05:04:09

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:03:30', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7e04d044-e34e-43e0-be6c-19def3c9870f'	System	17 Oct 2020 05:04:09
User entered 'None (0)'	System	17 Oct 2020 05:04:09

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:03:33', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7e04d044-e34e-43e0-be6c-19def3c9870f'	System	17 Oct 2020 05:04:09
User entered 'None (0)'	System	17 Oct 2020 05:04:09

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:03:36', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7e04d044-e34e-43e0-be6c-19def3c9870f'	System	17 Oct 2020 05:04:09
User entered 'None (0)'	System	17 Oct 2020 05:04:09

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:03:39', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7e04d044-e34e-43e0-be6c-19def3c9870f'	System	17 Oct 2020 05:04:09
User entered 'None (0)'	System	17 Oct 2020 05:04:09

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:04:01', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7e04d044-e34e-43e0-be6c-19def3c9870f'	System	17 Oct 2020 05:04:09
User entered 'No (N)'	System	17 Oct 2020 05:04:09

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T01:04:05', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7e04d044-e34e-43e0-be6c-19def3c9870f'	System	17 Oct 2020 05:04:09
User entered '17 Oct 2020 01:04'	System	17 Oct 2020 05:04:09

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 16:45'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 2'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:20:03', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7d67f52f-5630-4067-bd2e-e7ae908099ce'	System	17 Oct 2020 21:21:29
User entered 'None (0)'	System	17 Oct 2020 21:21:29

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:20:12', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7d67f52f-5630-4067-bd2e-e7ae908099ce'	System	17 Oct 2020 21:21:29
User entered 'None (0)'	System	17 Oct 2020 21:21:29

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:20:22', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7d67f52f-5630-4067-bd2e-e7ae908099ce'	System	17 Oct 2020 21:21:29
User entered 'None (0)'	System	17 Oct 2020 21:21:29

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:20:37', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7d67f52f-5630-4067-bd2e-e7ae908099ce'	System	17 Oct 2020 21:21:29
User entered 'None (0)'	System	17 Oct 2020 21:21:29

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:20:43', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7d67f52f-5630-4067-bd2e-e7ae908099ce'	System	17 Oct 2020 21:21:29
User entered 'None (0)'	System	17 Oct 2020 21:21:29

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:20:48', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7d67f52f-5630-4067-bd2e-e7ae908099ce'	System	17 Oct 2020 21:21:29
User entered 'None (0)'	System	17 Oct 2020 21:21:29

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:21:01', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7d67f52f-5630-4067-bd2e-e7ae908099ce'	System	17 Oct 2020 21:21:29
User entered 'No (N)'	System	17 Oct 2020 21:21:29

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-17T17:21:28', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: '7d67f52f-5630-4067-bd2e-e7ae908099ce' User entered '17 Oct 2020 17:21'	System	17 Oct 2020 21:21:29
	System	17 Oct 2020 21:21:29

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 3'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:11:41', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a430eb02-6920-4126-a1df-b6e37f9a6c39'	System	18 Oct 2020 23:13:16
User entered 'None (0)'	System	18 Oct 2020 23:13:16

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:11:44', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a430eb02-6920-4126-a1df-b6e37f9a6c39' User entered 'None (0)'	System	18 Oct 2020 23:13:16
	System	18 Oct 2020 23:13:16

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:11:51', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a430eb02-6920-4126-a1df-b6e37f9a6c39' User entered 'None (0)'	System	18 Oct 2020 23:13:16
	System	18 Oct 2020 23:13:16

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:11:55', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a430eb02-6920-4126-a1df-b6e37f9a6c39' User entered 'None (0)'	System	18 Oct 2020 23:13:16
	System	18 Oct 2020 23:13:16

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:12:31', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a430eb02-6920-4126-a1df-b6e37f9a6c39'	System	18 Oct 2020 23:13:16
User entered 'None (0)'	System	18 Oct 2020 23:13:16

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:12:55', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a430eb02-6920-4126-a1df-b6e37f9a6c39' User entered 'None (0)'	System	18 Oct 2020 23:13:16
	System	18 Oct 2020 23:13:16

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:13:06', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a430eb02-6920-4126-a1df-b6e37f9a6c39'	System	18 Oct 2020 23:13:16
User entered 'No (N)'	System	18 Oct 2020 23:13:16

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-18T19:13:12', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a430eb02-6920-4126-a1df-b6e37f9a6c39' User entered '18 Oct 2020 19:13'	System	18 Oct 2020 23:13:16
	System	18 Oct 2020 23:13:16

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 4'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:12', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a96e8edc-b2d8-4c5d-85db-371ea3febf02'	System	19 Oct 2020 21:52:50
User entered 'None (0)'	System	19 Oct 2020 21:52:50

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:15', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a96e8edc-b2d8-4c5d-85db-371ea3febf02'	System	19 Oct 2020 21:52:50
User entered 'None (0)'	System	19 Oct 2020 21:52:50

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:18', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a96e8edc-b2d8-4c5d-85db-371ea3febf02'	System	19 Oct 2020 21:52:50
User entered 'None (0)'	System	19 Oct 2020 21:52:50

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:22', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a96e8edc-b2d8-4c5d-85db-371ea3febf02'	System	19 Oct 2020 21:52:50
User entered 'None (0)'	System	19 Oct 2020 21:52:50

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:24', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a96e8edc-b2d8-4c5d-85db-371ea3febf02'	System	19 Oct 2020 21:52:50
User entered 'None (0)'	System	19 Oct 2020 21:52:50

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:26', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a96e8edc-b2d8-4c5d-85db-371ea3febf02'	System	19 Oct 2020 21:52:50
User entered 'None (0)'	System	19 Oct 2020 21:52:50

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:43', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a96e8edc-b2d8-4c5d-85db-371ea3febf02'	System	19 Oct 2020 21:52:50
User entered 'No (N)'	System	19 Oct 2020 21:52:50

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-19T17:52:46', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'a96e8edc-b2d8-4c5d-85db-371ea3febf02'	System	19 Oct 2020 21:52:50
User entered '19 Oct 2020 17:52'	System	19 Oct 2020 21:52:50

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 5'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:15', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd72a69bc-0516-415b-9e5e-28dfd7388c84'	System	21 Oct 2020 01:11:41
User entered 'None (0)'	System	21 Oct 2020 01:11:41

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:18', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd72a69bc-0516-415b-9e5e-28dfd7388c84'	System	21 Oct 2020 01:11:41
User entered 'None (0)'	System	21 Oct 2020 01:11:41

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:21', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd72a69bc-0516-415b-9e5e-28dfd7388c84' User entered 'None (0)'	System	21 Oct 2020 01:11:41
	System	21 Oct 2020 01:11:41

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:23', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd72a69bc-0516-415b-9e5e-28dfd7388c84' User entered 'None (0)'	System	21 Oct 2020 01:11:41
	System	21 Oct 2020 01:11:41

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:27', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd72a69bc-0516-415b-9e5e-28dfd7388c84'	System	21 Oct 2020 01:11:41
User entered 'None (0)'	System	21 Oct 2020 01:11:41

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:30', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd72a69bc-0516-415b-9e5e-28dfd7388c84'	System	21 Oct 2020 01:11:41
User entered 'None (0)'	System	21 Oct 2020 01:11:41

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:36', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd72a69bc-0516-415b-9e5e-28dfd7388c84'	System	21 Oct 2020 01:11:41
User entered 'No (N)'	System	21 Oct 2020 01:11:41

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-20T21:11:39', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'd72a69bc-0516-415b-9e5e-28dfd7388c84' User entered '20 Oct 2020 21:11'	System	21 Oct 2020 01:11:41
	System	21 Oct 2020 01:11:41

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 6'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:51', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'aaa1d9d2-a542-4350-a5e2-60ad01532906'	System	22 Oct 2020 00:07:31
User entered 'None (0)'	System	22 Oct 2020 00:07:31

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:54', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'aaa1d9d2-a542-4350-a5e2-60ad01532906'	System	22 Oct 2020 00:07:31
User entered 'None (0)'	System	22 Oct 2020 00:07:31

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:06:59', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'aaa1d9d2-a542-4350-a5e2-60ad01532906'	System	22 Oct 2020 00:07:31
User entered 'None (0)'	System	22 Oct 2020 00:07:31

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:07:04', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'aaa1d9d2-a542-4350-a5e2-60ad01532906'	System	22 Oct 2020 00:07:31
User entered 'None (0)'	System	22 Oct 2020 00:07:31

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:07:09', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'aaa1d9d2-a542-4350-a5e2-60ad01532906'	System	22 Oct 2020 00:07:31
User entered 'None (0)'	System	22 Oct 2020 00:07:31

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:07:17', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'aaa1d9d2-a542-4350-a5e2-60ad01532906'	System	22 Oct 2020 00:07:31
User entered 'None (0)'	System	22 Oct 2020 00:07:31

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:07:24', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'aaa1d9d2-a542-4350-a5e2-60ad01532906'	System	22 Oct 2020 00:07:31
User entered 'No (N)'	System	22 Oct 2020 00:07:31

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-21T20:07:29', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'aaa1d9d2-a542-4350-a5e2-60ad01532906'	System	22 Oct 2020 00:07:31
User entered '21 Oct 2020 20:07'	System	22 Oct 2020 00:07:31

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 17:06:58
User entered 'Day 7'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:39', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'cf43e02a-eaef-48bf-a485-232715bd45de'	System	23 Oct 2020 00:57:05
User entered 'None (0)'	System	23 Oct 2020 00:57:05

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:41', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'cf43e02a-eaef-48bf-a485-232715bd45de' User entered 'None (0)'	System	23 Oct 2020 00:57:05
	System	23 Oct 2020 00:57:05

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:45', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'cf43e02a-eaef-48bf-a485-232715bd45de'	System	23 Oct 2020 00:57:05
User entered 'None (0)'	System	23 Oct 2020 00:57:05

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:48', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'cf43e02a-eaef-48bf-a485-232715bd45de' User entered 'None (0)'	System	23 Oct 2020 00:57:05

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:51', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'cf43e02a-eaef-48bf-a485-232715bd45de'	System	23 Oct 2020 00:57:05
User entered 'None (0)'	System	23 Oct 2020 00:57:05

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:56:53', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'cf43e02a-eaef-48bf-a485-232715bd45de' User entered 'None (0)'	System	23 Oct 2020 00:57:05

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:40

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 (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:57:01', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'cf43e02a-eaef-48bf-a485-232715bd45de'	System	23 Oct 2020 00:57:05
User entered 'No (N)'	System	23 Oct 2020 00:57:05

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (38991BC6-14DE-427C-AE6D-4167DD7A710B)', Time: '2020-10-22T20:57:03', User OID: 'PatientReportedOutcome (US3482284)', ODM File OID: 'cf43e02a-eaef-48bf-a485-232715bd45de' User entered '22 Oct 2020 20:57'	System	23 Oct 2020 00:57:05
	System	23 Oct 2020 00:57:05

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 17:06:58

US3482284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 17:06:58

US3482284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 20:25:35

US3482284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:40

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 20:25:35

US3482284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Oct 2020 20:25:35

US3482284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 20:25:35

US3482284

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 20:26:00

US3482284

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 20:26:00

US3482284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 23:08:02

US3482284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	06 Nov 2020 23:08:32
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	06 Nov 2020 23:08:32
User entered '30 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 23:08:32
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	06 Nov 2020 23:08:02
User entered '6 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 23:08:02

US3482284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Nov 2020 23:08:02

US3482284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 23:08:02

US3482284

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 23:08:38

US3482284

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 23:08:38

US3482284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 23:08:49

US3482284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '06 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 13:32:25
User entered '6 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 23:08:49

US3482284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Nov 2020 23:08:49

US3482284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 23:08:49

US3482284

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 23:08:55

US3482284

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 23:08:55

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '04 Dec 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '08 Dec 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '11 Dec 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '15 Dec 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '18 Dec 2022 00:01'	System	20 Nov 2020 12:13:30

US3482284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:13:30
Amendment Manager: User entered '22 Dec 2022 23:59'	System	20 Nov 2020 12:13:30

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:32:40

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020'	Hollie Macenczak (b) (4)	13 Nov 2020 20:46:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:32:40

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '16:00'	Hollie Macenczak (b) (4)	13 Nov 2020 20:46:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:32:40

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020 16:00'	System	13 Nov 2020 20:46:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:32:40

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Safety Call (Safety Call)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:46:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:32:40

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:46:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	Hollie Macenczak (b) (4) [REDACTED]	20 Nov 2020 15:40:12
User entered empty.	Hollie Macenczak (b) (4) [REDACTED]	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.6' F	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:40:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Severe (Severe)' reason for change: Data Entry Error	Hollie Macenczak (b) (4) [REDACTED]	20 Nov 2020 15:46:57
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4) [REDACTED]	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:41:12

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Severe (Severe)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:42:05

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '05 Nov 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:46:57

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '6 Nov 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:47:33

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '7 Nov 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

Fatigue

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '8 Nov 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

Fatigue

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '9 Nov 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:49:38

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 18 (Day 18)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '14 Nov 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '93'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered '96.8' F	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:51:53

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 19 (Day 19)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '15 Nov 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.7' F	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 15:53:32

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 20 (Day 20)'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[Date](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '96'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.6' F	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[Cough](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:32:40

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Hollie Macenczak (b) (4)	20 Nov 2020 16:13:06

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:40

[Date of Visit](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:28

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:40

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:28

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:40

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:59
Query 'Data is required. Please complete.' answered with 'TEST PENDING' (Site from System).	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:38
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 20:48:28
User entered empty.	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:28

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:40

[Date of Test](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:28

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:40

Type of Test Performed

Audit	User	Time (GMT)
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:28

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:40

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:28

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:40

Was this diagnostic test performed at a lab other than the Study Central Lab?

Audit	User	Time (GMT)
User entered 'No (N)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:28

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:40

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:28

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:40

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	13 Nov 2020 20:48:28

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:40

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 17:39:59

US3482284

Folder: Covid-19 Assessment 12 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:32:40

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:46:12

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:32:40

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:32:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:32:40

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '15 Nov 2020'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:32:40

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:32:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:32:40

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:32:40

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:32:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:32:40

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:32:40

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:32:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:32:40

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:32:40

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:32:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:32:40

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:32:40

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:32:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:32:40

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:32:40

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:32:40

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:32:40

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:39:39

US3482284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:42:50

US3482284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Hollie Macenczak (b) (4)	13 Nov 2020 20:42:50

US3482284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:42:50

US3482284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	13 Nov 2020 20:42:50

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '10:34'	Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '13 Nov 2020 10:34'	System	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

Height (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51
DataPoint set to visible.	System	13 Nov 2020 20:42:50

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

Weight (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51
DataPoint set to visible.	System	13 Nov 2020 20:42:50

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.6' F	Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '89'	Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '26'	Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '134'	Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '98'	Hollie Macenczak (b) (4)	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Nov 2020 20:43:51

US3482284

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:43:58

US3482284

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Hollie Macenczak (b) (4)	13 Nov 2020 20:43:58

US3482284

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:32:40

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	13 Nov 2020 20:44:05

US3482284

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:32:40

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	Hollie Macenczak (b) (4)	13 Nov 2020 20:44:05

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:36:06

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:36:06

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:36:06

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	19 Nov 2020 17:36:06

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:36:10

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:36:10

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:36:10

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:36:10

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:36:10

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:36:10

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:36:10

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:36:10

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:36:10

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:36:10

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:36:10

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:36:10

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:36:10

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:36:10

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 17:36:10

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:36:16

US3482284

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:36:16

US3482284

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:32:40

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Hollie Macenczak (b) (4)	19 Nov 2020 17:36:23

US3482284

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:32:40

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	19 Nov 2020 17:36:23

US3482284

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:32:40

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:35:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'USA-US106-2020-mRNA-1273-P301000002'	System	02 Nov 2020 21:18:05
User entered 'New'	(b) (4), (b) (6)	02 Nov 2020 21:18:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:07:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:07:54
Data point term sent to Coder	System	30 Oct 2020 20:37:45
User entered 'Myocardial Infarction'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:33:56
User entered '27 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:56:55
User entered '28 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:53:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 13:38:38
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date provided' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:09:44
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	10 Nov 2020 20:53:30
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	10 Nov 2020 20:53:30
User entered '31 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:53:30
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	10 Nov 2020 20:52:36
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 18:59:01
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:33:56
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:41:22
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 22:07:14
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 12:26:01
	(b) (4), (b) (6)	11 Nov 2020 16:58:41
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject has not been discharged yet, Medical records have been requested' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 21:04:07
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	30 Oct 2020 20:37:10
User entered '1'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:56:55
User entered '28 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '31 Oct 2020' reason for change: New Information	Michele McCullough	06 Nov 2020 15:36:36
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Yes (Y)' reason for change: New Information	Michele McCullough (b) (4)	06 Nov 2020 15:36:36
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '1' reason for change: New Information	Michele McCullough	06 Nov 2020 15:36:36
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:41:29
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 22:07:14
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:49:45
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 22:07:14
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
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)	11 Nov 2020 13:38:45
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 'no action has been taken at this time.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:10:09
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)	09 Nov 2020 19:01:13
User entered 'None (NONE)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '1'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '1'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
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)	11 Nov 2020 13:38:51
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 'outcome is entered' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:10:40
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 20:52:36
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)	09 Nov 2020 18:59:19
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	10 Nov 2020 21:56:55
User entered 'SHORTNESS OF BREATH & IMPAIRED CARDIAC FUNCTION (CHF)' reason for change: Per Query Resolution	(b) (4), (b) (6)	10 Nov 2020 21:56:55
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	10 Nov 2020 20:52:36
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:37:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 12:24:43
User closed query 'PV Query: Please clarify whether the event of acute on chronic systolic heart failure refers to the sequela of the event of myocardial infarction which is described as Impaired cardiac function (CHF).' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 14:30:47
Query 'PV Query: Please clarify whether the event of acute on chronic systolic heart failure refers to the sequela of the event of myocardial infarction which is described as Impaired cardiac function (CHF).' answered with 'acute on chronic systolic heart failure was a new diagnosis that described the sequellae of the STEMI and exacerbation of the sequellae' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 21:24:17
User opened query 'PV Query: Please clarify whether the event of acute on chronic systolic heart failure refers to the sequela of the event of myocardial infarction which is described as Impaired cardiac function (CHF).' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 18:09:15
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 13:39:12
User closed query 'PV Query: Please provide the symptoms on the start date of the event.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 13:39:07
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)	11 Nov 2020 13:39:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 13:38:57
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 'DETAILS OF MEDS AND INTERVENTIONS IN NARRATIVE AS LISTED AND CON MEDS UPDATED IN DCF AND eCRF' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 22:53:48
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so' answered with 'AWAITING CONFIRMATION OF TEST PERFORMED. VERBAL REPORT OF NEGATIVE TEST BY SUBJECT BUT NO RESULT SEEN IN ADMISSION RECORDS OR DISCHARGE SUMMARY.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 22:40:30
Query 'PV Query: Please provide the symptoms on the start date of the event.' answered with 'HEARTBURN AND SHORTNESS OF BREATH' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 22:39:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WITH CHEST PAIN BEGINNING 28OCT2020. INITIALLY THOUGHT IT WAS INDIGESTION DUE TO DINNER FROM PREVIOUS NIGHT. IT PERSISTED TO 29OCT2020, AND PT STARTED HAVING DIZZINESS AND SHORTNESS OF BREATH WITH CLIMBING A LADDER FOR WORK, SO SUBJECT WENT TO ED. EKG REVEALED ST ELEVATION Mi AND LABS SHOWED ELEVATED TROPONIN (MAX 45.5). WAS TREATED WITH NTG, ASAS, AND HEPARIN IV. SUBJECT UNDERWENT EMERGENT CARDIAC CATHETERIZATION WITH UNSUCCESSFUL THROMBECTOMY & ANGIOPLASTY TO TOTALLY OCCLUDED MID RCA. HE WAS TRANSFERRED TO ICU FOR ONGOING CARE. WAS TREATED WITH INTEGRILIN DRIP, MORPHINE FOR PAIN, AND CONTINUED BASELINE STATINS, BETA BLOCKER, AND AMLODIPINE. WAS NOTED TO HAVE RENAL IMPAIRMENT ON ADMISSION LABS. COVID PCR WAS NEGATIVE.PARTICIPANT IMPROVED DURING ADMISSION AND WAS D/C'D TO RETURN TO ATLANTA FOR F/U WITH REGULAR CARDIOLOGIST FOR FURTHER MANAGEMENT.' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:33:56
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'records have been sent.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:13:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT NOTICED CHEST PAIN BEGINNING 28OCT2020. IT PERSISTED INTO 29OCT2020 SO SUBJECT WENT TO ED WHERE EKG REVEALED ST ELEVATION. SUBJECT UNDERWENT CARDIAC CATHETERIZATION WITH UNSUCCESSFUL PCI TO TOTALLY OCCLUDED MID RCA. He was transferred to ICU for ongoing care. Was prescribed Integrillin drip for residual chest pain and pressure. Prescribed morphine for pain SUBJECT TO FOLLOW UP WITH CARDIOLOGIST. COVID PCR was negative.'	(b) (4), (b) (6)	10 Nov 2020 19:53:53
reason for change: New Information		
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 19:01:47
User opened query 'PV Query: Please provide the symptoms on the start date of the event.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 19:01:28
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)	09 Nov 2020 19:00:42
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 19:00:26
User entered 'Subject noticed chest pain beginning 28OCT2020. It persisted into 29OCT2020 so subject went to ED where EKG revealed ST elevation. Subject underwent cardiac catheterization with unsuccessful PCI to totally occluded mid RCA. Subject to follow up with cardiologist.' reason for change: New Information	Michele McCullough (b) (4)	06 Nov 2020 15:36:36

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered with 'Awaiting medical records for further clarification' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 21:05:42
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	30 Oct 2020 20:37:10
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 15:36:36
User entered '0'	System	30 Oct 2020 20:37:10

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 13:40:47
User entered 'USA-US106-2020-mRNA-1273-P301000002'	(b) (4), (b) (6)	11 Nov 2020 13:40:41

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:54:44
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:08:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:08:39
Data point term sent to Coder	System	11 Nov 2020 22:08:16
User entered 'SHORTNESS OF BREATH' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 22:07:40
Data point term sent to Coder	System	11 Nov 2020 21:56:56
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 21:55:59
Coding entries removed.	(b) (4), (b) (6)	11 Nov 2020 21:55:59
User entered 'SHORTNESS FO BREATH' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 21:55:59
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User coded data point as SOC: Cardiac disorders, HLG: Heart failures, HLT: Left ventricular failures, PT: Chronic left ventricular failure, LLT: Chronic systolic heart failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:17:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:17:41
Data point term sent to Coder	System	10 Nov 2020 21:36:09
User entered 'SHORTNESS FO BREATH DUE TO ACUTE EXACERBATION OF CHRONIC SYSTOLIC HEART FAILURE'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '28 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 21:02:21
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Participant is again hospitalized for further exacerbation -- should we await disposition and discharge before answering query?' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 20:46:57
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 18:00:18
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 21:35:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 21:35:36
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:35:36
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 21:35:18
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '5 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '7 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'None (NONE)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered '1'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[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)	18 Nov 2020 21:02:26
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 'Participant is again hospitalized for further exacerbation -- will update as info is available.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 20:47:30
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)	16 Nov 2020 17:59:21
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify the chronic status of the event of acute on chronic systolic heart failure. Did the subject have chronic (systolic) heart failure as medical history? If so, please list it in the medical history.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 14:31:10
Query 'PV Query: Please clarify the chronic status of the event of acute on chronic systolic heart failure. Did the subject have chronic (systolic) heart failure as medical history? If so, please list it in the medical history.' answered with 'The participant did not report a prior history of heart failure and does not even endorse that now as a diagnosis. He just reports that he had a clot in his heart. His long ter medical records are still being reviewed and received to gain additional reliable information.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 21:26:22
User opened query 'PV Query: Please clarify the chronic status of the event of acute on chronic systolic heart failure. Did the subject have chronic (systolic) heart failure as medical history? If so, please list it in the medical history.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 18:08:19
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:58:41

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT WITH SOB SINCE SYMPTOM ONSET PRIOR TO DIAGNOSED MYOCARDIAL INFARCTION 31 OCT. WAS SEEN AT PCP FOR REGULAR FOLLOW UP 5 NOV, AND HAD SOB THAT MD DEEMED SIGNIFICANT ENOUGH TO REFER PT TO ER FOR ECHOCARDIOGRAM AND EVAL. PT WAS SEEN AT ER, ADMITTED TO HOSPITAL, TRANSFERRED TO ICU PER HIS REPORT. CARDIAC PROCEDURE/SURGERY OF UNKNOWN TYPE WAS OFFERED TO PARTICIPANT WHO DECLINED, WANTING TO CONSULT HIS OWN CARDIOLOGIST. THEREAFTER PARTICIPANT WAS DISCHARGED/LEFT AMA AND IS AWAITING FURTHER OUTPATIENT IMAGING AND EVALUATION THIS WEEK TO DECIDE NEXT STEPS. WE ARE AWAITING FULL HOSPITAL D/C RECORDS AT THIS TIME. PT CURRENTLY NOTES SOB AT REST, WITH INCREASED TALKING. HAD 3 NEGATIVE COVID TESTS SINCE LAST IN CLINIC AND WILL HAVE AN ILLNESS VISIT HERE 13 NOV 2020.' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:37:40
User entered 'PARTICIPANT WITH SOB SINCE SYMPTOM ONSET PRIOR TO DIAGNOSED MYOCARDIAL INFARCTION 31 OCT. WAS SEEN AT PCP FOR REGULAR FOLLOW UP 5 NOV, AND HAD SOB THAT MD DEEMED SIGNIFICANT ENOUGH TO REFER PT TO ER FOR ECHOCARDIOGRAM AND EVAL. PT WAS SEEN AT ER, ADMITTED TO HOSPITAL, TRANSFERRED TO ICU PER HIS REPORT. CARDIAC PROCEDURE/SURGERY OF UNKNOWN TYPE WAS OFFERED TO PARTICIPANT WHO DECLINED, WANTING TO CONSULT HIS OWN CARDIOLOGIST. THEREAFTER PARTICIPANT WAS DISCHARGED/LEFT AMA AND IS AWAITING FURTHER OUTPATIENT IMAGING AND EVALUATION THIS WEEK TO DECIDE NEXT STEPS.'	(b) (4), (b) (6)	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:35:36

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:35:18

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:25:00
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:05:24
User entered 'USA-US106-2020-mRNA-1273-P301000002'	(b) (4), (b) (6)	12 Nov 2020 15:05:19

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:27:26
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Left ventricular failures, PT: Acute left ventricular failure, LLT: Acute systolic heart failure - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 03:00:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 03:00:39
Data point term sent to Coder	System	11 Nov 2020 22:04:06
User entered 'ACUTE ON CHRONIC SYSTOLIC HEART FAILURE'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:27:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Query 'The source notes this response as "no"; please review and update RDC.' answered with 'response changed to "no"' (Site from CRA).	Hollie Macenczak (b) (4)	24 Nov 2020 21:03:49
User entered 'No (N)' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	24 Nov 2020 20:58:31
User opened query 'The source notes this response as "no"; please review and update RDC.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 18:04:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:29:17
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:29:14
User entered '5 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:29:29
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:29:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:29:47
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 21:00:40
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Participant again hospitalized 16 NOV for further exacerbation and is still admitted. Will update as further info is available.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 20:49:09
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 18:00:50
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:29:52
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:29:56
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:30:00
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:30:07
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:30:04
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		11 Nov 2020 22:04:05
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		11 Nov 2020 22:04:05
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 22:04:05
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	11 Nov 2020 22:03:41
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:30:15
User entered '5 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:30:17
User entered '7 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:30:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:30:22
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	11 Nov 2020 22:04:05
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	11 Nov 2020 22:04:05
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	11 Nov 2020 22:03:41
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:31:51
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:31:54
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:31:56
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:31:59
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:32:02
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:32:20
User closed query 'PV Query: Please confirm the action taken as it was reported as study drug withdrawn. As study drug was already withdrawn to earlier MI, please update to "not applicable"' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 14:34:00
Query 'PV Query: Please confirm the action taken as it was reported as study drug withdrawn. As study drug was already withdrawn to earlier MI, please update to "not applicable"' answered with 'Updated' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 19:09:48
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 19:07:39
User opened query 'PV Query: Please confirm the action taken as it was reported as study drug withdrawn. As study drug was already withdrawn to earlier MI, please update to "not applicable"' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 18:05:25
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:32:43
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:32:44
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:32:46
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:32:53
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)	18 Nov 2020 21:00:54
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 'Participant rehospitalized 16 NOV for further exacerbation. Still admitted. Will update as info becomes available.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 20:49:55
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)	16 Nov 2020 17:59:39
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:32:58
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm that chronic kidney disease is included in medical history. If so, please list it in the medical history. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 21:02:02
User closed query 'PV Query: Please confirm if echocardiogram was performed. If so, please provide results.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 21:01:54
User closed query 'PV Query: Please send a hospital discharge summary for the 05 Nov 2020 hospitalization with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 21:01:35
Query 'PV Query: Please confirm that chronic kidney disease is included in medical history. If so, please list it in the medical history. If not, please explain.' answered with 'ADDED.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 21:44:20
Query 'PV Query: Please confirm if echocardiogram was performed. If so, please provide results.' answered with '5 NOV 2020 echo performed; reported: "LVEF severely depressed. Calculated EF=29%. Regional wall motion abnormalities noted. Dilated RV with with severe RV dysfunction. Moderate to severe mitral regurgitation. Moderate to severe tricuspid regurg. A prior echo was conducted 20 FEB 2020. Compared to prior study, LV EF is lower today (on 5 NOV). There is more mitral and tricuspid insufficiency as well.'" (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 21:44:10
Query 'PV Query: Please send a hospital discharge summary for the 05 Nov 2020 hospitalization with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Copy previously sent by CRC on AM of 13 NOV. Please confirm it was not received and we will resend.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 21:02:24
User opened query 'PV Query: Please confirm that chronic kidney disease is included in medical history. If so, please list it in the medical history. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 18:07:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if echocardiogram was performed. If so, please provide results.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 18:06:28
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 18:06:02
User opened query 'PV Query: Please send a hospital discharge summary for the 05 Nov 2020 hospitalization with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 18:03:41
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)	16 Nov 2020 18:02:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT WITH SOB SINCE SYMPTOM ONSET PRIOR TO DIAGNOSED MYOCARDIAL INFARCTION 31 OCT. WAS SEEN AT PCP FOR REGULAR FOLLOW UP 5 NOV, AND HAD SOB THAT MD DEEMED SIGNIFICANT ENOUGH TO REFER PT TO ER FOR ECHOCARDIOGRAM AND EVAL. PT WAS SEEN AT ER, ADMITTED TO HOSPITAL, TRANSFERRED TO ICU PER HIS REPORT. CARDIAC PROCEDURE/SURGERY OF UNKNOWN TYPE WAS OFFERED TO PARTICIPANT WHO DECLINED, WANTING TO CONSULT HIS OWN CARDIOLOGIST. THEREAFTER PARTICIPANT WAS DISCHARGED/LEFT AMA AND IS AWAITING FURTHER OUTPATIENT IMAGING AND EVALUATION THIS WEEK TO DECIDE NEXT STEPS. WE ARE STILL AWAITING FULL HOSPITAL D/C RECORDS AT THIS TIME. NO REPORT OF CHF IN PMHx PRIOR TO HEART ATTACK IN LATE OCTOBER.'	(b) (4), (b) (6)	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 22:03:41

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:37:08
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:45:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 21:45:03
Data point term sent to Coder	System	20 Nov 2020 21:44:06
User entered 'chest pain'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:37:13
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:37:15
User entered 'No (N)'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:37:19
User entered 'No (N)'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:37:24
User entered '16 Nov 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:37:27
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:37:29
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:37:30
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:37:32
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:37:41
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 21:44:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 21:44:49
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Hollie Macenczak (b) (4)	20 Nov 2020 21:44:49
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 21:43:16
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:37:58
User entered 'Yes (Y)'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:38:04
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:38:09
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: Thank you for the response. Please provide discharge date once the data available. Leave the query open till the update is made else respond to clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 04:43:39
User closed query 'Per CDM RQ: Thank you for the response. Once, subject is discharged, please update Hospital Discharge Date appropriately, else clarify.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 04:43:26
Query 'Per CDM RQ: Thank you for the response. Once, subject is discharged, please update Hospital Discharge Date appropriately, else clarify.' answered with 'Subject discharged on 20NOV2020 - medical records are pending at this time. No discharge summary to date.' (Site from DM).	Hollie Macenczak (b) (4)	23 Nov 2020 16:18:21
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 13:43:54
User opened query 'Per CDM RQ: Thank you for the response. Once, subject is discharged, please update Hospital Discharge Date appropriately, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:43:53
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject has no discharge date as he is still admitted.' (Site from System).	Hollie Macenczak (b) (4)	20 Nov 2020 21:44:37
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	20 Nov 2020 21:43:16
User entered '1'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:40:59
User entered '18 Nov 2020'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:41:05
User entered 'No (N)'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:41:11
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:41:14
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:41:16
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:41:28
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:41:31
User entered 'Not Related (NOT RELATED)'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:41:33
User entered 'Not Related (NOT RELATED)'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:41:34
User entered 'Not Applicable (NOT APPLICABLE)'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:41:43
User entered '1'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:41:44
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:41:46
User entered '0'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:41:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:42:08
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:42:23
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Nov 2020 21:47:08
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	20 Nov 2020 21:47:08
User entered 'Subject began having chest pain after safety call was completed on 16NOV2020 and sought medical attention in ED. Team was notified on 19NOV2020 of admission to hospital for evaluation of "arrhythmia" and "flutter" per subject description. Medical records pending.' reason for change: New Information	Hollie Macenczak (b) (4)	20 Nov 2020 21:47:08
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Nov 2020 21:43:16
User entered empty.	Hollie Macenczak (b) (4)	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 21:43:16

US3482284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '0'	System	20 Nov 2020 21:43:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:32:40

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:37:40
User closed query 'Per ETRTR: Medications and procedures were done for SAE "Myocardial Infarction" according to SAE CRF. Please update ConMeds and ConProceudres as applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 21:04:17
Query 'Per ETRTR: Medications and procedures were done for SAE "Myocardial Infarction" according to SAE CRF. Please update ConMeds and ConProceudres as applicable, thanks.' answered with 'New meds and d/c'd meds updated and ongoing' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 16:29:59
User opened query 'Per ETRTR: Medications and procedures were done for SAE "Myocardial Infarction" according to SAE CRF. Please update ConMeds and ConProceudres as applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 20:32:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 20:21:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:04:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:04:40
Data point term sent to Coder	System	19 Oct 2020 16:03:42
User entered 'Atorvastatin'	(b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	(b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	(b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	06 Nov 2020 17:42:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	06 Nov 2020 17:42:31
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	06 Nov 2020 17:42:25
User entered '30 Oct 2020' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	06 Nov 2020 17:42:25
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:03:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:05:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:05:41
Data point term sent to Coder	System	19 Oct 2020 16:04:44
User entered 'Metoprolol'	(b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	(b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	(b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:04:13

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:06:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:06:45
Data point term sent to Coder	System	19 Oct 2020 16:05:46
User entered 'Losartan'	(b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	(b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	(b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:05:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

[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) (b) (4)	19 Oct 2020 16:07:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:07:34
Data point term sent to Coder	System	19 Oct 2020 16:06:50
User entered 'Aspirin'	(b) (4), (b) (6) (b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'Heart Health'	(b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	(b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	(b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:06:07

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 10:19:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 10:19:32
Data point term sent to Coder	System	19 Oct 2020 16:07:52
User entered 'Triameterene HCTZ'	(b) (4), (b) (6) (b) (4)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	(b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '37.5/25'	(b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 16:30:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '5 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 16:30:38
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:07:10

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:09:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:09:24
Data point term sent to Coder	System	19 Oct 2020 16:08:52
User entered 'Amlodipine'	(b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	(b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	(b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 16:30:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	10 Nov 2020 16:30:58
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	10 Nov 2020 16:28:41
User entered '5 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 16:28:41
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:08:16

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: EMTRICITABINE;TENOFOVIR ALAFENAMIDE FUMARATE, PRODUCTSYNONYM: DESCOVY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:11:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:11:21
Data point term sent to Coder	System	19 Oct 2020 16:09:55
User entered 'Descovy'	(b) (4), (b) (6) (b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'HIV Prophylaxis'	(b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	(b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	(b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:09:21

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 16:12:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 16:12:24
Data point term sent to Coder	System	19 Oct 2020 16:10:56
User entered 'Zolpidem'	(b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'Insomnia'	(b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	(b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	(b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:10:31

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 10:21:10
Data point term sent to Coder	System	19 Oct 2020 16:11:59
User entered 'Red Volt Pre-Workout Supplement'	(b) (4), (b) (6) (b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'Weight Loss'	(b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2'	(b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'capsule (CAPSULE)'	(b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'un Mar 2020'	(b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:11:43

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: ANDROGRAPHIS PANICULATA;ECHINACEA PURPUREA ROOT;OLEA EUROPAEA LEAF, PRODUCTSYNONYM: IMMUNE SUPPORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:23:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:23:20
Data point term sent to Coder	System	19 Oct 2020 16:14:02
User entered 'Immune Support Vitamin'	(b) (4), (b) (6) (b) (4)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'Health Maintenance'	(b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered 'un Mar 2020'	(b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:13:24

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

[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: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 08:19:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 08:19:28
Data point term sent to Coder	System	06 Nov 2020 17:52:55
User entered 'Heparin'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'AE # 1 (mYOCARDIAL INFARCTION)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5000'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'UNITS'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:52:09

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 08:31:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 08:31:28
Data point term sent to Coder	System	06 Nov 2020 18:03:14
User entered 'Nitroglycerine'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'Myocardial infarction (AE#1)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'Mg/250 ml'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:02:15

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

[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) (b) (4)	06 Nov 2020 21:09:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:09:24
Data point term sent to Coder	System	06 Nov 2020 18:04:17
User entered 'Aspirin'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'AE#1 (myocardial infarction)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '325'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	06 Nov 2020 18:03:34
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	06 Nov 2020 18:03:34
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	06 Nov 2020 18:03:18
User entered 'once (ONCE)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '29 Oct 2020' reason for change: Data Entry Error	Sarah Bechnak (b) (4)	06 Nov 2020 18:03:34
User entered '20 Oct 2020'	Sarah Bechnak (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 18:03:18

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

[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: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:46:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:46:23
Data point term sent to Coder	System	06 Nov 2020 18:05:18
User entered 'Clopidogrel'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'AE#1 (myocardial infarction)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '75'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 18:04:30

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 18:08:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 18:08:20
Data point term sent to Coder	System	06 Nov 2020 18:07:23
User entered 'Seroquel'	Sarah Bechnak (b) (4)	06 Nov 2020 18:06:53
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'insomnia'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '200'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 18:06:53

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 18:09:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 18:09:21
Data point term sent to Coder	System	06 Nov 2020 18:08:24
User entered 'seroquel'	Sarah Bechnak (b) (4)	06 Nov 2020 18:07:56
	(b) (4)	

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'insomnia'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '31 Oct 2020'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 18:07:56

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 18:10:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 18:10:25
Data point term sent to Coder	System	06 Nov 2020 18:09:25
User entered 'Atorvastatin'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'hyperlipidemia'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

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

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sarah Bechnak (b) (4) (b) (4)	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:32:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 18:08:40

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:32:40

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 22:54:07

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:32:40

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 22:55:48

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:32:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'CARDIAC CATHETERIZATION WITH ANGIOGRAPHY AND PERCUTANEOUS CORONARY INTERVENTION'	(b) (4), (b) (6)	10 Nov 2020 22:55:48

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:32:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	10 Nov 2020 22:55:48

US3482284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:32:40

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 22:55:48

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
User entered 'Nadine' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 14:25:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
User entered 'Rouphael' reason for change: Data	(b) (4)	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
User entered 'Nadine' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 14:25:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
User entered 'Rouphael' reason for change: Data	(b) (4)	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:32:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
User entered '02/Nov/2020 16:18'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:32:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered '1'	(b) (4), (b) (6)	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
User entered 'Rouphael' reason for change: Data	(b) (4)	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:32:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
User entered '09/Nov/2020 19:50'	System	09 Nov 2020 19:50:36

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:32:40

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)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 19:50:36

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
User entered 'Rouphael' reason for change: Data	(b) (4)	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:32:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:52:16
User entered '11/Nov/2020 13:41'	System	11 Nov 2020 13:41:17

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:32:40

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)	24 Nov 2020 18:52:28
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 13:41:17

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
User entered 'Nadine' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 14:25:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
User entered 'Rouphael' reason for change: Data	(b) (4)	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:32:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '12/Nov/2020 15:06'	System	12 Nov 2020 15:06:28

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:32:40

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)	17 Nov 2020 14:34:22
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 15:06:28

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
User entered 'Nadine' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 14:25:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
User entered 'Rouphael' reason for change: Data	(b) (4)	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:32:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '17/Nov/2020 14:34'	System	17 Nov 2020 14:34:34

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:32:40

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)	18 Nov 2020 21:05:42
User entered '1'	(b) (4), (b) (6)	17 Nov 2020 14:34:34

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'USA-US106-2020-MRNA-1273-P301000002'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:36:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Yes (Y)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:36:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:06:07
Un-reviewed for Safety.	System	11 Nov 2020 22:07:14
DataPoint Un-verified.	System	11 Nov 2020 22:07:14
User entered 'Yes (Y)'	System	11 Nov 2020 22:07:14
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'No (N)'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Easton'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
User entered 'Nadine' reason for change: Data Entry Error	Michele McCullough	06 Nov 2020 14:25:29
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Easton'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 13:41:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Un-reviewed for Safety.	System	09 Nov 2020 19:50:36
User entered 'Beshears'	System	09 Nov 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
Un-reviewed for Safety.	Michele McCullough	06 Nov 2020 14:25:29
User entered 'Rouphael' reason for change: Data	(b) (4)	06 Nov 2020 14:25:29
Entry Error	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 21:18:24
User entered 'Beshears'	System	02 Nov 2020 21:18:05

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered empty.	Michele McCullough (b) (4)	06 Nov 2020 14:25:29

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:13:40
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 19:50:26
User entered 'US'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	18 Nov 2020 21:05:54
User entered '5'	System	17 Nov 2020 14:34:34
User entered '4'	System	12 Nov 2020 15:06:28
User entered '3'	System	11 Nov 2020 13:41:17
User entered '2'	System	09 Nov 2020 19:50:36
User entered '1'	System	02 Nov 2020 21:18:32

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:32:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '18/Nov/2020 21:05'	System	18 Nov 2020 21:05:54

US3482284

Folder: SAE USA-US106-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:32:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 21:05:54