

US3402382 (Prod: Meridian Clinical Research, LLC)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:28:09

All time stamps listed in this document are displayed in GMT

US3402382

Form: Participant Creation

Generated On: 26 Nov 2020 09:28:09

[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 09:28:09

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 AUG 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 09:28:09

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	66
Age Units	YEARS
Age (Derived)	67
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:09

Date of Informed Consent (<i>dd MMM yyyy</i>)	16 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:28:09

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:28:09

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:09

Condition	TYPE 2 DIABETES
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 (2)

Generated On: 26 Nov 2020 09:28:09

Condition	TORN ACL RIGHT LEG
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:09

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:09

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:09

Condition	GOUT
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:09

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	25 AUG 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:09

Condition	BENIGN PROSTATIC HYPERTROPHY
Start date (dd MMM yyyy)	01 SEP 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:09

Condition	BILATERAL HIP OSTEOARTHRITIS
Start date (dd MMM yyyy)	25 APR 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)	APR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:09

Condition	ANXIETY
Start date (dd MMM yyyy)	05 NOV 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)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:09

Condition	CONSTIPATION
Start date (dd MMM yyyy)	04 NOV 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)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	16 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:21 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 12:21
Height (<i>xxx.x</i>)	74 in
Weight (<i>xxx.x</i>)	282 lb
BMI (<i>xxx.x</i>)	36.28236 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	98.1 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>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 AUG 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 09:28:09

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 TOWN (b) (6)

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 09:28:09

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 AUG 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 09:28:09

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

What was the participant's randomization number? 186501

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 09:28:09

Height	74 in
Weight	282 lb

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

Height	74 in
Weight	282 lb
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	16 AUG 2020
Time of assessment (00:00-23:59)	12:21 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 12:21
Temperature (xxx.x)	36.3 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 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 09:28:09

Height	74 in
Weight	282 lb
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	16 AUG 2020
Time of assessment (00:00-23:59)	13:45 (24 HR)
Vital Signs Date and Time (derived)	16 AUG 2020 13:45
Temperature (xxx.x)	36.4 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:09

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 09:28:09

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 AUG 2020
What was the treatment time? (00:00-23:59)	13:13 (24 HR)
Treatment Date and Time (derived)	16 AUG 2020 13:13
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 09:28:09

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	16 AUG 2020
Collection time (<i>00:00-23:59</i>)	12:39 (24 HR)
Collection date and time (derived)	16 AUG 2020 12:39

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:28:09

Collection date (<i>dd MMM yyyy</i>)			16 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:37	16 AUG 2020 12:37
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

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 09:28:09

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

96.0 °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 AUG 2020 13:47

PC Open Date & Time

16 AUG 2020 13:33

PC Close Date & Time

16 AUG 2020 16:03

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

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 94.5 °F

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

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

PC Time Stamp	16 AUG 2020 21:45
PC Open Date & Time	16 AUG 2020 16:58
PC Close Date & Time	17 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 20:30

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:09

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

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

18 AUG 2020 13:23

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 19:17

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:09

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

21 AUG 2020 16:29

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

23 AUG 2020 10:54

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

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 AUG 2020 13:48

PC Open Date & Time

16 AUG 2020 13:33

PC Close Date & Time

16 AUG 2020 16:03

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

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

16 AUG 2020 21:46

PC Open Date & Time

16 AUG 2020 16:58

PC Close Date & Time

17 AUG 2020 11:59

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:09

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:09

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 AUG 2020 13:25

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:09

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 AUG 2020 19:18

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:09

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:09

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 AUG 2020 16:28

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:09

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

23 AUG 2020 10:55

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

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

No ☒

Yes ☐

PC Time stamp	16 AUG 2020 13:49
PC Open Date & Time	16 AUG 2020 13:33
PC Close Date & Time	16 AUG 2020 16:03

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

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

No ☒

Yes ☐

PC Time stamp	16 AUG 2020 21:47
PC Open Date & Time	16 AUG 2020 16:58
PC Close Date & Time	17 AUG 2020 11:59

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:09

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

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:09

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 ☒

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:09

Yes ☐	
PC Time stamp	18 AUG 2020 13:26
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:09

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 ☒

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:09

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

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:09

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

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:09

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 ☒

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:09

Yes ☐	
PC Time stamp	21 AUG 2020 16:29
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:09

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 ☒

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:09

Yes ☐	
PC Time stamp	23 AUG 2020 10:56
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3402382

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 23 AUG 2020 23:15

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3402382

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp 24 AUG 2020 19:22

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

US3402382

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	23 AUG 2020 23:15
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3402382

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	24 AUG 2020 19:22
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3402382

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

Was Contact Attempted?

Yes ☒

No ☐

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

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402382

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402382

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402382

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402382

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402382

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402382

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 11:30
Temperature (xxx.x)	36.3 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	12:35 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 12:35
Temperature (xxx.x)	36.4 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3402382

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3402382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

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)	14 SEP 2020
What was the treatment time? (00:00-23:59)	12:03 (24 HR)
Treatment Date and Time (derived)	14 SEP 2020 12:03
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

US3402382

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:09

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	14 SEP 2020
Collection time (<i>00:00-23:59</i>)	11:46 (24 HR)
Collection date and time (derived)	14 SEP 2020 11:46

US3402382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:28:09

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:43	14 SEP 2020 11:43
Nasopharyngeal Swab 2	No		

US3402382

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

14 SEP 2020 12:35

PC Open Date & Time

14 SEP 2020 12:23

PC Close Date & Time

14 SEP 2020 14:53

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 14 SEP 2020 15:48

PC Close Date & Time 15 SEP 2020 11:59

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:09

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:09

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:09

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:09

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:09

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:09

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

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

14 SEP 2020 12:36

PC Open Date & Time

14 SEP 2020 12:23

PC Close Date & Time

14 SEP 2020 14:53

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

PC Open Date & Time

14 SEP 2020 15:48

PC Close Date & Time

15 SEP 2020 11:59

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:09

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:09

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:09

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:09

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:09

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:09

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 12:37
PC Open Date & Time	14 SEP 2020 12:23
PC Close Date & Time	14 SEP 2020 14:53

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

14 SEP 2020 15:48

PC Close Date & Time

15 SEP 2020 11:59

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:09

		Yes ☐
PC Time stamp		
PC Open Date & Time		15 SEP 2020 12:00
PC Close Date & Time		16 SEP 2020 11:59

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:09

		Yes ☐
PC Time stamp		
PC Open Date & Time		16 SEP 2020 12:00
PC Close Date & Time		17 SEP 2020 11:59

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:09

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

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:09

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

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:09

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

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:09

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

US3402382

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402382

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402382

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

Was Contact Attempted?

Yes ☒

No ☐

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

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402382

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402382

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402382

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402382

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3402382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	12 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:32 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 12:32
Temperature (<i>xxx.x</i>)	97.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402382

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:09

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.

US3402382

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:09

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	12 OCT 2020
Collection time (<i>00:00-23:59</i>)	12:35 (24 HR)
Collection date and time (derived)	12 OCT 2020 12:35

US3402382

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 OCT 2020 08:25:33

Patient Cloud Open Date & Time

16 OCT 2020 00:01

Patient Cloud Close Date & Time

20 OCT 2020 23:59

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 OCT 2020 11:08:41

Patient Cloud Open Date & Time

23 OCT 2020 00:01

Patient Cloud Close Date & Time

27 OCT 2020 23:59

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	31 OCT 2020 11:07:29
Patient Cloud Open Date & Time	30 OCT 2020 00:01
Patient Cloud Close Date & Time	03 NOV 2020 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2020 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2020 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2020 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2020 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2020 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

DAY 96

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 12:20:42

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 07:51:05

Patient Cloud Open Date & Time

24 NOV 2020 00:01

Patient Cloud Close Date & Time

28 NOV 2020 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2020 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2020 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2020 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2020 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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02 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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

Date and time of submission

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13 FEB 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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

Date and time of submission

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16 FEB 2021 00:01

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20 FEB 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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

Date and time of submission

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13 MAR 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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

Date and time of submission

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16 MAR 2021 00:01

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20 MAR 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 MAR 2021 00:01

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27 MAR 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

[Patient Cloud Close Date & Time](#)

10 APR 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

[Patient Cloud Close Date & Time](#)

13 NOV 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

20 NOV 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 NOV 2021 00:01

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27 NOV 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

11 DEC 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

18 DEC 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

25 DEC 2021 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JAN 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JAN 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JAN 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JAN 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JAN 2022 00:01

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29 JAN 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 FEB 2022 00:01

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05 FEB 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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08 FEB 2022 00:01

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12 FEB 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

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19 FEB 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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

Date and time of submission

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26 FEB 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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

Date and time of submission

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05 MAR 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

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](#)

29 MAR 2022 00:01

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02 APR 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

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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

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05 APR 2022 00:01

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09 APR 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

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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](#)

12 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 APR 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

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

Date and time of submission

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19 APR 2022 00:01

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23 APR 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 APR 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2022 23:59

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2022 23:59

US3402382

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402382

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402382

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402382

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:09

Date of Contact	26 AUG 2020
Time of Contact	07:00
Date and Time of Contact (derived)	26 AUG 2020 07:00
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 ☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	26 AUG 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	99.5 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)	343 of 2497	

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	27 AUG 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	347 of 2497	

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	28 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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)	351 of 2497	

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	29 AUG 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Fatigue	None	☐
v6.020 DTW (1102)	355 of 2497	

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

	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	☒

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	30 AUG 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Fatigue	None	☐
v6.020 DTW (1102)	359 of 2497	

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

	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	☒

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	31 AUG 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Fatigue	None	☐
v6.020 DTW (1102)	363 of 2497	

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

	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	☒

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	01 SEP 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☒
Fatigue	None	☐
v6.020 DTW (1102)	367 of 2497	

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

	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	☒

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	02 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.8 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)	371 of 2497	

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	03 SEP 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	36.1 C	
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)	375 of 2497	

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	04 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	96.4 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)	379 of 2497	

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	05 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	96.0 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)	383 of 2497	

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	06 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	96.9 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)	387 of 2497	

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	07 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	36.4 C	
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)	391 of 2497	

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	08 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	96.4 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)	395 of 2497	

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	09 SEP 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	96.9 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)	399 of 2497	

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	10 SEP 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.9 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)	403 of 2497	

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	11 SEP 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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)	407 of 2497	

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	12 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.4 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)	411 of 2497	

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	13 OCT 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)	415 of 2497	

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

	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	☐

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:09

Date of Visit	26 AUG 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	26 AUG 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

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:28:09

[Generate Next COVID-19 Assessment](#)

Yes ☐
No ☒

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:28:09

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	28 AUG 2020
Day 5	No	
Day 7	No	
Day 9	Yes	03 SEP 2020
Day 14	Yes	08 SEP 2020
Day 21	No	
Day 28	No	

US3402382

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3402382

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	26 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:51 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 12:51
Height (<i>xxx.x</i>)	187.9 cm
Weight (<i>xxx.x</i>)	127.9 kg
Temperature (<i>xxx.x</i>)	99.5 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	137 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402382

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

US3402382

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:28:09

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 AUG 2020

US3402382

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

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 _____

US3402382

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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)	

US3402382

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:09

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.

US3402382

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:28:09

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection _____

US3402382

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:28:09

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3402382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

AEID	USA-US059-2020-MRNA-1273-P30 1000002
Adverse event	ATRIAL FIBRILLATION
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	28 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	1 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	28 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	1 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	430 of 2497

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

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

US3402382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

SUBJECT PRESENTED IN
OFFICE 26/AUG/2020 FOR A
CONVALESCENT DAY 1 VISIT.
HIS PULSE WAS NOTED TO BE
139. HE ALSO STATED THAT HE
THOUGHT HE WAS HAVING
SYMPTOMS OF AN URINARY
INFECTION. HE WAS ADVISED
TO GO TO THE EMERGENCY
ROOM AT THAT POINT. WHICH
HE DECLINED. HE WAS GIVEN
LEVOFLOXACIN 500MG PO FOR
10 DAYS. WHEN HE CAME TO
LEAVE HIS DAY 3 SALIVA
SAMPLE2 28OCT2020 IT WAS
NOTED THAT THE PATIENT
WAS NOT ANY BETTER.
PATIENT STATED THAT HE
WAS UNSTEADY ON HIS FEET
AND HAD FALLEN PRIOR TO
COMING TO DROP OFF SAMPLE.
IT WAS AGAIN RECOMMENDED
THAT THE SUBJECT GO TO THE
ER. WHICH HE DID.DUE TO
SUBJECT FALLING HE HAD A
CT OF THE HEAD AND BRAIN,
THAT WERE NEGATIVE. ALSO
A CHEST X-RAY THAT WAS
NEGATIVE. SUBJECTS BLOOD
PRESSURE IN THE ER WAS 86/70
HEART RATE 134 AND A RESP
RATE OF 20. SUBJECT HAS
VARIOUS LABS, OF NOTE WERE
CRP 14, CO2 20, BUN 36,
CREATININE 1.9. IT WAS
THOUGHT THAT HE HAD
UROSEPSIS AND WAS STARTED

US3402382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

ON ROCEPHIN, WHILE
AWAITING URINE AND BLOOD
CULTURE RESULTS WHICH
WERE NEGATIVE. SUBJECT
WAS ADMITTED 28AUG2020
WITH A DIAGNOSIS OF ATRIAL
FLUTTER. A CONULT WITH
CARDIOLOGY WAS
CONDUCTED, AND PATIENT
WAS STARTED ON 5 MG
ELIQUIS DAILY AND WILL
FOLLOW UP ON AN OUT
PATIENT BASIS. COVID 19 TEST
PREFORMED 26AUG2020 WITH
A NEGATIVE RESULT.
SUBJECTS HEART RATE HAS
RETURNED TO NORMAL WITH
THE HELP OF MEDICATION
WHICH IS CAPTURES ON THE
CONMED LOG.

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

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

AEID	
Adverse event	URINARY TRACT INFECTION
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)	26 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	6 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

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

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:28:09

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

Yes ☒

No ☐

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

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

Name of Medication	GLIMEPIRIDE
Prophylaxis	Yes ☐ No ☒
Indication	DIABETES TYPE 2
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 ☐ Intramuscular ☐

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

	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)		21 JUL 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	☒

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

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

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

	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)	25 AUG 2008	
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	☒

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

Name of Medication	VIAGARA
Prophylaxis	Yes ☐ No ☒
Indication	ERECTILE DYSFUNCTION
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 ☐

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

	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)		25 AUG 2008
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	☐

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

Name of Medication	METOPROLOL ER
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 ☐

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

	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)		25 APR 2008
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	☒

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

	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)		10 FEB 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	☒

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

Name of Medication	TAMSULOSIN
Prophylaxis	Yes ☐ No ☒
Indication	BENIGN PROSTATIC HYPERTROPHY
Dose per administration	0.4
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

	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)		01 SEP 2017
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

Name of Medication	FEBUXOSTAT
Prophylaxis	Yes ☐ No ☒
Indication	GOUT
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 ☐

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

	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)		25 OCT 2017
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

Name of Medication	VOLTAREN 1%
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOARTHRITIS BILATERAL HIPS
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 ☐

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

	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)	25 APR 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	☒

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

Name of Medication	OZEMPIC
Prophylaxis	Yes ☐ No ☒
Indication	DIABETES TYPE 2
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 ☐

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		05 NOV 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	☐

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

Name of Medication	DULOXETINE
Prophylaxis	Yes ☐ No ☒
Indication	ANXIETY
Dose per administration	60
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 ☐

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		05 NOV 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	☒

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

Name of Medication	JARDIANCE
Prophylaxis	Yes ☐ No ☒
Indication	DIABETES TYPE 2
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 ☐

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		18 APR 2017
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

Name of Medication	HYDROCODONE
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOARTHRITIS
Dose per administration	5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

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

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

Name of Medication	COLACE
Prophylaxis	Yes ☐ No ☒
Indication	CONSTIPATION
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 ☐

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

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

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

Name of Medication	LANTUS SOLOSTAR
Prophylaxis	Yes ☐ No ☒
Indication	TYPE 2 DIABETES
Dose per administration	100
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 ☐ Intramuscular ☐

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

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

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

Name of Medication	ELIQUIS
Prophylaxis	Yes ☐ No ☒
Indication	ATRIAL FIBRILLATION
Dose per administration	5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
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	☒

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

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

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	08 SEP 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	☒

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

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

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	06 SEP 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 ☒	

US3402382

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:28:09

[Were any concomitant procedures performed?](#)

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3402382

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:28:09

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

US3402382

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:28:09

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 ☐

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

SAEID	USA-US059-2020-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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:28:09

SAEID	USA-US059-2020-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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	02/SEP/2020 09:12
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

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:28:09

SAEID	USA-US059-2020-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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	14/SEP/2020 16:29
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

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:28:09

SAEID	USA-US059-2020-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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	30/SEP/2020 17:21
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

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:28:09

SAEID	USA-US059-2020-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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	30/OCT/2020 14:04
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

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:28:09

SAEID	USA-US059-2020-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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	02/NOV/2020 14:29
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

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:28:09

SAEID	USA-US059-2020-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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	09/NOV/2020 11:14
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

US3402382 (Prod: Meridian Clinical Research, LLC)

US3402382

Form: Participant Creation

Generated On: 26 Nov 2020 09:28:09

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3402382'	RWS_ENDPOINT ENDPOINT (b) (4) 	16 Aug 2020 16:29:15

US3402382

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:16:25

US3402382

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '16 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	16 Aug 2020 16:29:16

US3402382

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:16:25

US3402382

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	16 Aug 2020 17:16:25

US3402382

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	16 Aug 2020 16:29:17

US3402382

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:09

[Age](#)

Audit	User	Time (GMT)
User entered '66'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:09

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	17 Aug 2020 11:53:44

US3402382

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:09

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '67'	System	16 Aug 2020 17:17:02

US3402382

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:09

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:09

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:09

[White](#)

Audit	User	Time (GMT)
User entered '1'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:09

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:09

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:09

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:09

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:09

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:09

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:09

Unknown

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:28:09

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:53:44

US3402382

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '16 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:02

US3402382

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	16 Aug 2020 17:17:02

US3402382

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '2020'	System	16 Aug 2020 17:17:02

US3402382

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:09

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:02

US3402382

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:02

US3402382

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:02

US3402382

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:09

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:02

US3402382

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:09

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:02

US3402382

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:09

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	16 Aug 2020 16:29:16

US3402382

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:28:09

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Aug 2020 17:17:08

US3402382

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:08

US3402382

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:28:09

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:54:27

US3402382

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:09

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 12:00:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 12:00:19
Data point term sent to Coder	System	17 Aug 2020 11:55:16
User entered 'TYPE 2 DIABETES'	Traci Hull (b) (4)	17 Aug 2020 11:54:50
	(b) (4)	

US3402382

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'UN UNK 1995'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:54:50

US3402382

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:54:50

US3402382

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:54:50

US3402382

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:54:50

US3402382

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:54:50

US3402382

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	17 Aug 2020 11:54:50

US3402382

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '1995'	System	17 Aug 2020 11:54:50

US3402382

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 11:54:50

US3402382

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 11:54:50

US3402382

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:09

[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: Ligament rupture, LLT: Anterior cruciate ligament tear - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 07:08:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 07:08:14
Data point term sent to Coder	System	17 Aug 2020 11:55:15
User entered 'TORN ACL RIGHT LEG'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:10

US3402382

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:10

US3402382

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:10

US3402382

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:10

US3402382

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:10

US3402382

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:10

US3402382

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	17 Aug 2020 11:55:10

US3402382

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '2008'	System	17 Aug 2020 11:55:10

US3402382

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 11:55:10

US3402382

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 11:55:10

US3402382

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:09

[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 Aug 2020 12:02:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 12:02:45
Data point term sent to Coder	System	17 Aug 2020 11:56:16
User entered 'HYPERLIPIDEMIA'	Traci Hull (b) (4)	17 Aug 2020 11:55:26
	(b) (4)	

US3402382

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:26

US3402382

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:26

US3402382

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:26

US3402382

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:26

US3402382

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:26

US3402382

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	17 Aug 2020 11:55:26

US3402382

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '2010'	System	17 Aug 2020 11:55:26

US3402382

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 11:55:26

US3402382

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 11:55:26

US3402382

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:09

[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)	17 Aug 2020 12:02:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 12:02:45
Data point term sent to Coder	System	17 Aug 2020 11:56:16
User entered 'HYPERTENSION'	Traci Hull (b) (4)	17 Aug 2020 11:55:39
	(b) (4)	

US3402382

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'UN UNK 2000'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:39

US3402382

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:39

US3402382

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:39

US3402382

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:39

US3402382

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:39

US3402382

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	17 Aug 2020 11:55:39

US3402382

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '2000'	System	17 Aug 2020 11:55:39

US3402382

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 11:55:39

US3402382

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 11:55:39

US3402382

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:09

Condition

Audit	User	Time (GMT)
User closed query 'CDM RQ: Per previous query response, please update the Condition Term to include the location.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:40:08
Query 'CDM RQ: Per previous query response, please update the Condition Term to include the location.' answered with ' LEFT FOOT' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 18:03:22
User opened query 'CDM RQ: Per previous query response, please update the Condition Term to include the location.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:11:56
User closed query 'Per DM CLR: Please specify the location of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:11:56
Query 'Per DM CLR: Please specify the location of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'LEFT BIG TOE' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	22 Sep 2020 18:02:07
User opened query 'Per DM CLR: Please specify the location of GOUT. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 04:12:56
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:02:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:02:46
Data point term sent to Coder	System	17 Aug 2020 11:56:16
User entered 'GOUT'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:48

US3402382

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'UN UNK 2008'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:48

US3402382

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:48

US3402382

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:48

US3402382

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:48

US3402382

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:55:48

US3402382

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Jan 2008'	System	17 Aug 2020 11:55:48

US3402382

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '2008'	System	17 Aug 2020 11:55:48

US3402382

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 11:55:48

US3402382

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 11:55:48

US3402382

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:09

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLG: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 20:47:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 20:47:12
Data point term sent to Coder	System	17 Aug 2020 20:47:03
User entered 'ERECTILE DYSFUNCTION'	Traci Hull (b) (4)	17 Aug 2020 20:46:55

US3402382

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '25 Aug 2008'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:46:55

US3402382

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:46:55

US3402382

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:46:55

US3402382

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:46:55

US3402382

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:46:55

US3402382

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Aug 2008'	System	17 Aug 2020 20:46:55

US3402382

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '2008'	System	17 Aug 2020 20:46:55

US3402382

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 20:46:55

US3402382

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 20:46:55

US3402382

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:09

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:49:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:49:15
Data point term sent to Coder	System	17 Aug 2020 20:48:03
User entered 'BENIGN PROSTATIC HYPERTROPHY'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:47:24

US3402382

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '01 Sep 2017'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:47:24

US3402382

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:47:24

US3402382

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:47:24

US3402382

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:47:24

US3402382

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:47:24

US3402382

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Sep 2017'	System	17 Aug 2020 20:47:24

US3402382

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '2017'	System	17 Aug 2020 20:47:24

US3402382

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 20:47:24

US3402382

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 20:47:24

US3402382

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:09

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:49:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:49:15
Data point term sent to Coder	System	17 Aug 2020 20:48:04
User entered 'BILATERAL HIP OSTEOARTHRITIS'	Traci Hull (b) (4)	17 Aug 2020 20:48:01

US3402382

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '25 Apr 2018'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:01

US3402382

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:01

US3402382

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:01

US3402382

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:01

US3402382

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:01

US3402382

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Apr 2018'	System	17 Aug 2020 20:48:01

US3402382

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '2018'	System	17 Aug 2020 20:48:01

US3402382

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 20:48:01

US3402382

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 20:48:01

US3402382

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:09

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:50:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:50:16
Data point term sent to Coder	System	17 Aug 2020 20:49:04
User entered 'ANXIETY'	Traci Hull (b) (4)	17 Aug 2020 20:48:19
	(b) (4)	

US3402382

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '05 Nov 2018'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:19

US3402382

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:19

US3402382

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:19

US3402382

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:19

US3402382

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:19

US3402382

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Nov 2018'	System	17 Aug 2020 20:48:19

US3402382

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '2018'	System	17 Aug 2020 20:48:19

US3402382

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 20:48:19

US3402382

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 20:48:19

US3402382

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:09

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:50:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 20:50:16
Data point term sent to Coder	System	17 Aug 2020 20:49:04
User entered 'CONSTIPATION'	Traci Hull (b) (4)	17 Aug 2020 20:48:37

US3402382

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '04 Nov 2019'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:37

US3402382

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:37

US3402382

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 13:32:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 13:32:20
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 13:32:20
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 20:48:37
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:37

US3402382

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:37

US3402382

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:48:37

US3402382

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Nov 2019'	System	17 Aug 2020 20:48:37

US3402382

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '2019'	System	17 Aug 2020 20:48:37

US3402382

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 20:48:37

US3402382

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 20:48:37

US3402382

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

US3402382

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '16 Aug 2020'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

US3402382

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '12:21'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

US3402382

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:21'	System	17 Aug 2020 11:57:45

US3402382

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '74' in	Traci Hull (b) (4)	17 Aug 2020 11:57:45
DataPoint set to visible.	(b) (4) System	16 Aug 2020 17:17:08

US3402382

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '282' lb	Traci Hull (b) (4)	17 Aug 2020 11:57:45
DataPoint set to visible.	(b) (4) System	16 Aug 2020 17:17:08

US3402382

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '36.28236'	System	16 Sep 2020 23:59:08
User entered '36.3'	System	17 Aug 2020 11:57:45
DataPoint set to visible.	System	16 Aug 2020 17:17:08

US3402382

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	17 Aug 2020 11:57:45
DataPoint set to visible.	System	16 Aug 2020 17:17:08

US3402382

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

US3402382

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

US3402382

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

US3402382

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '89'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

US3402382

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Aug 2020 11:57:45

US3402382

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '14'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

US3402382

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Aug 2020 11:57:45

US3402382

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '100'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

US3402382

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 11:57:45

US3402382

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '62'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:57:45

US3402382

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 11:57:45

US3402382

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:58:08

US3402382

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	24 Sep 2020 10:23:49
Comment added 'PLEASE ADVISE ON RESOLUTION AS DATE IS CORRECT'.	Tammy Kohn (b) (4)	22 Sep 2020 15:16:23
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	14 Sep 2020 17:15:50
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	27 Aug 2020 13:32:50
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	26 Aug 2020 19:17:20
User entered '16 Aug 2020'	Traci Hull (b) (4)	17 Aug 2020 11:58:08

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

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)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

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)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

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)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

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)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

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)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

[Specify](#)

Audit	User	Time (GMT)
User entered 'TOWN' (b) (6)	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

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'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

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'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '1'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

Other

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:28:09

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 11:59:47

US3402382

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:00:26

US3402382

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '16 Aug 2020'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:00:26

US3402382

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:00:26

US3402382

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	17 Aug 2020 12:00:26

US3402382

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '16 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	16 Aug 2020 16:34:11

US3402382

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:09

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:54:19
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:54:19
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Aug 2020 16:34:11
User entered '186501' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	16 Aug 2020 16:34:11

US3402382

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	16 Aug 2020 16:34:11

US3402382

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:09

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)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:00:45

US3402382

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:00:45

US3402382

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:00:45

US3402382

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:09

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:00:45

US3402382

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:09

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:00:45

US3402382

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User closed query 'Per CDM: This field requires yes or no. Please complete' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:08:23
Query 'Per CDM: This field requires yes or no. Please complete' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4)	03 Nov 2020 13:01:46
User entered 'No (N)'	(b) (4)	03 Nov 2020 13:01:38
User opened query 'Per CDM: This field requires yes or no. Please complete' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:33:47
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:22:18
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:33:32

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:09

Height

Audit	User	Time (GMT)
User entered '74' in	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:09

Weight

Audit	User	Time (GMT)
User entered '282' lb	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:09

Height

Audit	User	Time (GMT)
User entered '74' in	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:09

Weight

Audit	User	Time (GMT)
User entered '282' lb	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Aug 2020'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '12:21'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:21'	System	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.3' C reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Sep 2020 12:15:36
User entered '98.1' F	Traci Hull (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '89'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '14'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '100'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '62'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:09

Height

Audit	User	Time (GMT)
User entered '74' in	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:28:09

Weight

Audit	User	Time (GMT)
User entered '282' lb	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Aug 2020'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 19:40:31
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 MINUTES' (Site from System).	Traci Hull (b) (4)	17 Aug 2020 12:02:24
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	17 Aug 2020 12:02:13
User entered '13:45'	Traci Hull (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '16 Aug 2020 13:45'	System	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

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	17 Sep 2020 12:14:55
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.' answered by data change (Site from System).	System	17 Sep 2020 12:14:55
User entered '36.4' C reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	17 Sep 2020 12:14:55
Amendment Manager: 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	16 Sep 2020 23:59:08
User entered '96.0' F	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '60'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '14'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '100'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '76'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 12:02:13

US3402382

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	18 Sep 2020 12:19:19
User entered 'Yes (Y)'	Traci Hull (b) (4)	17 Aug 2020 12:02:35

US3402382

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	18 Sep 2020 12:19:19
User entered '16 Aug 2020'	Traci Hull (b) (4)	17 Aug 2020 12:02:35

US3402382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	16 Aug 2020 17:17:49

US3402382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	16 Aug 2020 17:17:49
	(b) (4)	

US3402382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	16 Aug 2020 17:17:49
	(b) (4)	

US3402382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	16 Aug 2020 17:17:49

US3402382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Aug 2020'	Jennifer Molstead (b) (4)	16 Aug 2020 17:17:49
	(b) (4)	

US3402382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '13:13'	Jennifer Molstead (b) (4)	16 Aug 2020 17:17:49
	(b) (4)	

US3402382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '16 Aug 2020 13:13'	System	16 Aug 2020 17:17:49

US3402382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4)	16 Aug 2020 17:17:49
	(b) (4)	

US3402382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	16 Aug 2020 17:17:49

US3402382

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	16 Aug 2020 17:17:49

US3402382

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:04

US3402382

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Aug 2020'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:04

US3402382

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:09

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '12:39'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:04

US3402382

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:39'	System	17 Aug 2020 12:03:04

US3402382

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '16 Aug 2020'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:20

US3402382

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:09

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:20

US3402382

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:20

US3402382

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '12:37'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:20

US3402382

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:37'	System	17 Aug 2020 12:03:20

US3402382

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:09

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:20

US3402382

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:20

US3402382

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:20

US3402382

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 12:03:20

US3402382

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 12:03:25

US3402382

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 12:03:25

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:46:43', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '62fcd2c3-ff8f-42d3-84e1-1855ef735627'	System	16 Aug 2020 17:47:22
User entered 'Yes (Y)'	System	16 Aug 2020 17:47:22

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:47:01', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '62fcd2c3-ff8f-42d3-84e1-1855ef735627'	System	16 Aug 2020 17:47:22
User entered '96.0'	System	16 Aug 2020 17:47:22

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:47:09', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '62fcd2c3-ff8f-42d3-84e1-1855ef735627'	System	16 Aug 2020 17:47:22
User entered 'No (N)'	System	16 Aug 2020 17:47:22

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:47:19', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '62fcd2c3-ff8f-42d3-84e1-1855ef735627'	System	16 Aug 2020 17:47:22
User entered '16 Aug 2020 13:47'	System	16 Aug 2020 17:47:22

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 13:33'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 16:03'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 1, after vaccination (at home)'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:44:34', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '31ed431e-7ac6-4760-8add-820dd01d7f0f'	System	17 Aug 2020 01:45:12
User entered 'Yes (Y)'	System	17 Aug 2020 01:45:12

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:44:45', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '31ed431e-7ac6-4760-8add-820dd01d7f0f' User entered '94.5'	System	17 Aug 2020 01:45:12

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:44:56', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '31ed431e-7ac6-4760-8add-820dd01d7f0f'	System	17 Aug 2020 01:45:12
User entered 'No (N)'	System	17 Aug 2020 01:45:12

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:45:10', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '31ed431e-7ac6-4760-8add-820dd01d7f0f'	System	17 Aug 2020 01:45:12
User entered '16 Aug 2020 21:45'	System	17 Aug 2020 01:45:12

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 16:58'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 2'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-17T20:29:32', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ac33e71-88f1-44de-abcc-0d37b480faff'	System	18 Aug 2020 00:30:06
User entered 'Yes (Y)'	System	18 Aug 2020 00:30:06

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-17T20:29:43', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ac33e71-88f1-44de-abcc-0d37b480faff'	System	18 Aug 2020 00:30:06
User entered '98.0'	System	18 Aug 2020 00:30:06

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-17T20:29:50', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ac33e71-88f1-44de-abcc-0d37b480faff'	System	18 Aug 2020 00:30:06
User entered 'No (N)'	System	18 Aug 2020 00:30:06

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-17T20:30:03', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ac33e71-88f1-44de-abcc-0d37b480faff'	System	18 Aug 2020 00:30:06
User entered '17 Aug 2020 20:30'	System	18 Aug 2020 00:30:06

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 3'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:23:16', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'f2cd9b2d-a78d-4b2a-9f1e-22ede58b7e58'	System	18 Aug 2020 17:23:58
User entered 'Yes (Y)'	System	18 Aug 2020 17:23:58

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:23:31', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'f2cd9b2d-a78d-4b2a-9f1e-22ede58b7e58'	System	18 Aug 2020 17:23:58
User entered '98.0'	System	18 Aug 2020 17:23:58

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:23:36', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'f2cd9b2d-a78d-4b2a-9f1e-22ede58b7e58'	System	18 Aug 2020 17:23:58
User entered 'No (N)'	System	18 Aug 2020 17:23:58

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:23:55', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'f2cd9b2d-a78d-4b2a-9f1e-22ede58b7e58'	System	18 Aug 2020 17:23:58
User entered '18 Aug 2020 13:23'	System	18 Aug 2020 17:23:58

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 4'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:17:01', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '70cce1e5-f0dc-4dd6-a0f6-d4bd7b86555e'	System	19 Aug 2020 23:17:55
User entered 'Yes (Y)'	System	19 Aug 2020 23:17:55

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:17:17', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '70cce1e5-f0dc-4dd6-a0f6-d4bd7b86555e' User entered '98.1'	System	19 Aug 2020 23:17:55
	System	19 Aug 2020 23:17:55

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:17:24', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '70cce1e5-f0dc-4dd6-a0f6-d4bd7b86555e'	System	19 Aug 2020 23:17:55
User entered 'No (N)'	System	19 Aug 2020 23:17:55

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:17:53', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '70cce1e5-f0dc-4dd6-a0f6-d4bd7b86555e'	System	19 Aug 2020 23:17:55
User entered '19 Aug 2020 19:17'	System	19 Aug 2020 23:17:55

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 5'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 6'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:28:49', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'eff0d448-285c-4998-932f-cda24ebcb314'	System	21 Aug 2020 20:29:18
User entered 'Yes (Y)'	System	21 Aug 2020 20:29:18

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:01', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'eff0d448-285c-4998-932f-cda24ebcb314'	System	21 Aug 2020 20:29:18
User entered '98.3'	System	21 Aug 2020 20:29:18

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:08', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'eff0d448-285c-4998-932f-cda24ebcb314'	System	21 Aug 2020 20:29:18
User entered 'No (N)'	System	21 Aug 2020 20:29:18

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:15', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'eff0d448-285c-4998-932f-cda24ebcb314'	System	21 Aug 2020 20:29:18
User entered '21 Aug 2020 16:29'	System	21 Aug 2020 20:29:18

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 7'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:53:52', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '3f347bec-2d90-430a-a5ff-63051784b7d1'	System	23 Aug 2020 14:55:04
User entered 'Yes (Y)'	System	23 Aug 2020 14:55:04

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:54:37', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '3f347bec-2d90-430a-a5ff-63051784b7d1'	System	23 Aug 2020 14:55:04
User entered '98.3'	System	23 Aug 2020 14:55:04

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:54:42', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '3f347bec-2d90-430a-a5ff-63051784b7d1'	System	23 Aug 2020 14:55:04
User entered 'No (N)'	System	23 Aug 2020 14:55:04

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:54:58', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '3f347bec-2d90-430a-a5ff-63051784b7d1'	System	23 Aug 2020 14:55:04
User entered '23 Aug 2020 10:54'	System	23 Aug 2020 14:55:04

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:48:02', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0f25afb-5ef6-4765-a8de-3bb243704d6d'	System	16 Aug 2020 17:48:44
User entered 'None (1)'	System	16 Aug 2020 17:48:44

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:48:36', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0f25afb-5ef6-4765-a8de-3bb243704d6d'	System	16 Aug 2020 17:48:44
User entered 'No (N)'	System	16 Aug 2020 17:48:44

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:48:23', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0f25afb-5ef6-4765-a8de-3bb243704d6d'	System	16 Aug 2020 17:48:44
User entered 'No (N)'	System	16 Aug 2020 17:48:44

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:48:30', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0f25afb-5ef6-4765-a8de-3bb243704d6d'	System	16 Aug 2020 17:48:44
User entered 'None (1)'	System	16 Aug 2020 17:48:44

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:48:41', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0f25afb-5ef6-4765-a8de-3bb243704d6d' User entered '16 Aug 2020 13:48'	System	16 Aug 2020 17:48:44
	System	16 Aug 2020 17:48:44

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 13:33'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 16:03'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 1, after vaccination (at home)'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:45:35', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c0723321-64cd-4cec-b641-0ecb948bafb6'	System	17 Aug 2020 01:46:33
User entered 'None (1)'	System	17 Aug 2020 01:46:33

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:45:45', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c0723321-64cd-4cec-b641-0ecb948bafb6'	System	17 Aug 2020 01:46:33
User entered 'No (N)'	System	17 Aug 2020 01:46:33

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:45:52', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c0723321-64cd-4cec-b641-0ecb948bafb6'	System	17 Aug 2020 01:46:33
User entered 'No (N)'	System	17 Aug 2020 01:46:33

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:46:18', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c0723321-64cd-4cec-b641-0ecb948bafb6'	System	17 Aug 2020 01:46:33
User entered 'None (1)'	System	17 Aug 2020 01:46:33

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:46:30', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c0723321-64cd-4cec-b641-0ecb948bafb6'	System	17 Aug 2020 01:46:33
User entered '16 Aug 2020 21:46'	System	17 Aug 2020 01:46:33

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 16:58'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 2'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 3'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:09

[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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:24:31', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'e4c35dfb-4aca-4dd8-93fe-043c70fe9c6e'	System	18 Aug 2020 17:25:04
User entered 'None (1)'	System	18 Aug 2020 17:25:04

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:24:37', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'e4c35dfb-4aca-4dd8-93fe-043c70fe9c6e'	System	18 Aug 2020 17:25:04
User entered 'No (N)'	System	18 Aug 2020 17:25:04

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:24:40', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'e4c35dfb-4aca-4dd8-93fe-043c70fe9c6e'	System	18 Aug 2020 17:25:04
User entered 'No (N)'	System	18 Aug 2020 17:25:04

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:24:49', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'e4c35dfb-4aca-4dd8-93fe-043c70fe9c6e'	System	18 Aug 2020 17:25:04
User entered 'None (1)'	System	18 Aug 2020 17:25:04

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:25:01', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'e4c35dfb-4aca-4dd8-93fe-043c70fe9c6e'	System	18 Aug 2020 17:25:04
User entered '18 Aug 2020 13:25'	System	18 Aug 2020 17:25:04

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 4'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:18:05', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd6cebe28-fed4-4649-8cc5-c31ffa171106'	System	19 Aug 2020 23:18:36
User entered 'None (1)'	System	19 Aug 2020 23:18:36

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:18:12', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd6cebe28-fed4-4649-8cc5-c31ffa171106'	System	19 Aug 2020 23:18:36
User entered 'No (N)'	System	19 Aug 2020 23:18:36

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:18:18', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd6cebe28-fed4-4649-8cc5-c31ffa171106'	System	19 Aug 2020 23:18:36
User entered 'No (N)'	System	19 Aug 2020 23:18:36

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:18:25', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd6cebe28-fed4-4649-8cc5-c31ffa171106'	System	19 Aug 2020 23:18:36
User entered 'None (1)'	System	19 Aug 2020 23:18:36

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:18:34', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd6cebe28-fed4-4649-8cc5-c31ffa171106'	System	19 Aug 2020 23:18:36
User entered '19 Aug 2020 19:18'	System	19 Aug 2020 23:18:36

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 5'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 6'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:28:01', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd8eace2f-d4e6-4d08-a1f2-1c7888b73266'	System	21 Aug 2020 20:28:29
User entered 'None (1)'	System	21 Aug 2020 20:28:29

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:28:07', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd8eace2f-d4e6-4d08-a1f2-1c7888b73266'	System	21 Aug 2020 20:28:29
User entered 'No (N)'	System	21 Aug 2020 20:28:29

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:28:12', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd8eace2f-d4e6-4d08-a1f2-1c7888b73266'	System	21 Aug 2020 20:28:29
User entered 'No (N)'	System	21 Aug 2020 20:28:29

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:28:18', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd8eace2f-d4e6-4d08-a1f2-1c7888b73266'	System	21 Aug 2020 20:28:29
User entered 'None (1)'	System	21 Aug 2020 20:28:29

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:28:28', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd8eace2f-d4e6-4d08-a1f2-1c7888b73266'	System	21 Aug 2020 20:28:29
User entered '21 Aug 2020 16:28'	System	21 Aug 2020 20:28:29

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 7'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:55:12', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2a59c018-0871-4e34-84d9-2b11e799955c'	System	23 Aug 2020 14:55:45
User entered 'None (1)'	System	23 Aug 2020 14:55:45

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:55:18', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2a59c018-0871-4e34-84d9-2b11e799955c'	System	23 Aug 2020 14:55:45
User entered 'No (N)'	System	23 Aug 2020 14:55:45

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:55:25', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2a59c018-0871-4e34-84d9-2b11e799955c'	System	23 Aug 2020 14:55:45
User entered 'No (N)'	System	23 Aug 2020 14:55:45

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:55:32', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2a59c018-0871-4e34-84d9-2b11e799955c'	System	23 Aug 2020 14:55:45
User entered 'None (1)'	System	23 Aug 2020 14:55:45

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:55:40', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2a59c018-0871-4e34-84d9-2b11e799955c'	System	23 Aug 2020 14:55:45
User entered '23 Aug 2020 10:55'	System	23 Aug 2020 14:55:45

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:49:07', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ef84477-85ec-45d1-964e-dd76c206c371'	System	16 Aug 2020 17:49:51
User entered 'None (0)'	System	16 Aug 2020 17:49:51

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:49:13', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ef84477-85ec-45d1-964e-dd76c206c371'	System	16 Aug 2020 17:49:51
User entered 'None (0)'	System	16 Aug 2020 17:49:51

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:49:19', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ef84477-85ec-45d1-964e-dd76c206c371'	System	16 Aug 2020 17:49:51
User entered 'None (0)'	System	16 Aug 2020 17:49:51

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:49:22', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ef84477-85ec-45d1-964e-dd76c206c371'	System	16 Aug 2020 17:49:51
User entered 'None (0)'	System	16 Aug 2020 17:49:51

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:49:26', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ef84477-85ec-45d1-964e-dd76c206c371'	System	16 Aug 2020 17:49:51
User entered 'None (0)'	System	16 Aug 2020 17:49:51

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:49:33', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ef84477-85ec-45d1-964e-dd76c206c371'	System	16 Aug 2020 17:49:51
User entered 'None (0)'	System	16 Aug 2020 17:49:51

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:49:42', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ef84477-85ec-45d1-964e-dd76c206c371'	System	16 Aug 2020 17:49:51
User entered 'No (N)'	System	16 Aug 2020 17:49:51

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T13:49:47', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2ef84477-85ec-45d1-964e-dd76c206c371'	System	16 Aug 2020 17:49:51
User entered '16 Aug 2020 13:49'	System	16 Aug 2020 17:49:51

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 13:33'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 16:03'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 1, after vaccination (at home)'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:46:43', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '616c21e4-2974-4184-9e02-e74731e98aa9'	System	17 Aug 2020 01:47:42
User entered 'None (0)'	System	17 Aug 2020 01:47:42

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:46:49', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '616c21e4-2974-4184-9e02-e74731e98aa9'	System	17 Aug 2020 01:47:42
User entered 'None (0)'	System	17 Aug 2020 01:47:42

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:46:53', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '616c21e4-2974-4184-9e02-e74731e98aa9'	System	17 Aug 2020 01:47:42
User entered 'None (0)'	System	17 Aug 2020 01:47:42

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:46:58', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '616c21e4-2974-4184-9e02-e74731e98aa9'	System	17 Aug 2020 01:47:42
User entered 'None (0)'	System	17 Aug 2020 01:47:42

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:47:08', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '616c21e4-2974-4184-9e02-e74731e98aa9'	System	17 Aug 2020 01:47:42
User entered 'None (0)'	System	17 Aug 2020 01:47:42

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:47:14', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '616c21e4-2974-4184-9e02-e74731e98aa9'	System	17 Aug 2020 01:47:42
User entered 'None (0)'	System	17 Aug 2020 01:47:42

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:47:27', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '616c21e4-2974-4184-9e02-e74731e98aa9'	System	17 Aug 2020 01:47:42
User entered 'No (N)'	System	17 Aug 2020 01:47:42

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-16T21:47:40', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '616c21e4-2974-4184-9e02-e74731e98aa9'	System	17 Aug 2020 01:47:42
User entered '16 Aug 2020 21:47'	System	17 Aug 2020 01:47:42

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 16:58'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 2'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 3'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:25:12', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7e6d6a56-7211-4927-bd93-8e3843cac5dd'	System	18 Aug 2020 17:26:07
User entered 'None (0)'	System	18 Aug 2020 17:26:07

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:25:27', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7e6d6a56-7211-4927-bd93-8e3843cac5dd'	System	18 Aug 2020 17:26:07
User entered 'No interference with activity (1)'	System	18 Aug 2020 17:26:07

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:25:35', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7e6d6a56-7211-4927-bd93-8e3843cac5dd'	System	18 Aug 2020 17:26:07
User entered 'No interference with activity (1)'	System	18 Aug 2020 17:26:07

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:25:44', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7e6d6a56-7211-4927-bd93-8e3843cac5dd'	System	18 Aug 2020 17:26:07
User entered 'No interference with activity (1)'	System	18 Aug 2020 17:26:07

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:25:48', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7e6d6a56-7211-4927-bd93-8e3843cac5dd'	System	18 Aug 2020 17:26:07
User entered 'None (0)'	System	18 Aug 2020 17:26:07

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:25:53', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7e6d6a56-7211-4927-bd93-8e3843cac5dd'	System	18 Aug 2020 17:26:07
User entered 'None (0)'	System	18 Aug 2020 17:26:07

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:25:58', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7e6d6a56-7211-4927-bd93-8e3843cac5dd'	System	18 Aug 2020 17:26:07
User entered 'No (N)'	System	18 Aug 2020 17:26:07

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-18T13:26:05', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7e6d6a56-7211-4927-bd93-8e3843cac5dd'	System	18 Aug 2020 17:26:07
User entered '18 Aug 2020 13:26'	System	18 Aug 2020 17:26:07

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 4'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:19:18', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '18d71477-6c55-430f-8f8f-df0f6d1654ff'	System	19 Aug 2020 23:20:11
User entered 'None (0)'	System	19 Aug 2020 23:20:11

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:19:29', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '18d71477-6c55-430f-8f8f-df0f6d1654ff'	System	19 Aug 2020 23:20:11
User entered 'None (0)'	System	19 Aug 2020 23:20:11

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:19:34', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '18d71477-6c55-430f-8f8f-df0f6d1654ff'	System	19 Aug 2020 23:20:11
User entered 'None (0)'	System	19 Aug 2020 23:20:11

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:19:46', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '18d71477-6c55-430f-8f8f-df0f6d1654ff'	System	19 Aug 2020 23:20:11
User entered 'None (0)'	System	19 Aug 2020 23:20:11

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:19:51', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '18d71477-6c55-430f-8f8f-df0f6d1654ff'	System	19 Aug 2020 23:20:11
User entered 'None (0)'	System	19 Aug 2020 23:20:11

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:19:58', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '18d71477-6c55-430f-8f8f-df0f6d1654ff'	System	19 Aug 2020 23:20:11
User entered 'None (0)'	System	19 Aug 2020 23:20:11

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:20:03', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '18d71477-6c55-430f-8f8f-df0f6d1654ff'	System	19 Aug 2020 23:20:11
User entered 'No (N)'	System	19 Aug 2020 23:20:11

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-19T19:20:09', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '18d71477-6c55-430f-8f8f-df0f6d1654ff'	System	19 Aug 2020 23:20:11
User entered '19 Aug 2020 19:20'	System	19 Aug 2020 23:20:11

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 5'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 6'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:25', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1e0e7715-17c1-4222-9551-240956d6f9ea' User entered 'None (0)'	System	21 Aug 2020 20:30:02
	System	21 Aug 2020 20:30:02

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:32', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1e0e7715-17c1-4222-9551-240956d6f9ea' User entered 'None (0)'	System	21 Aug 2020 20:30:02
	System	21 Aug 2020 20:30:02

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:36', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1e0e7715-17c1-4222-9551-240956d6f9ea'	System	21 Aug 2020 20:30:02
User entered 'None (0)'	System	21 Aug 2020 20:30:02

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:40', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1e0e7715-17c1-4222-9551-240956d6f9ea' User entered 'None (0)'	System	21 Aug 2020 20:30:02
	System	21 Aug 2020 20:30:02

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:44', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1e0e7715-17c1-4222-9551-240956d6f9ea' User entered 'None (0)'	System	21 Aug 2020 20:30:02
	System	21 Aug 2020 20:30:02

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:49', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1e0e7715-17c1-4222-9551-240956d6f9ea'	System	21 Aug 2020 20:30:02
User entered 'None (0)'	System	21 Aug 2020 20:30:02

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:54', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1e0e7715-17c1-4222-9551-240956d6f9ea'	System	21 Aug 2020 20:30:02
User entered 'No (N)'	System	21 Aug 2020 20:30:02

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-21T16:29:57', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1e0e7715-17c1-4222-9551-240956d6f9ea'	System	21 Aug 2020 20:30:02
User entered '21 Aug 2020 16:29'	System	21 Aug 2020 20:30:02

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 7'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:55:59', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0856158-ec98-4db3-8070-3e1a7b55ff79'	System	23 Aug 2020 14:57:01
User entered 'None (0)'	System	23 Aug 2020 14:57:01

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:56:07', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0856158-ec98-4db3-8070-3e1a7b55ff79'	System	23 Aug 2020 14:57:01
User entered 'Some interference with activity (2)'	System	23 Aug 2020 14:57:01

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:56:15', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0856158-ec98-4db3-8070-3e1a7b55ff79'	System	23 Aug 2020 14:57:01
User entered 'None (0)'	System	23 Aug 2020 14:57:01

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:56:21', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0856158-ec98-4db3-8070-3e1a7b55ff79'	System	23 Aug 2020 14:57:01
User entered 'None (0)'	System	23 Aug 2020 14:57:01

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:56:41', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0856158-ec98-4db3-8070-3e1a7b55ff79'	System	23 Aug 2020 14:57:01
User entered 'None (0)'	System	23 Aug 2020 14:57:01

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:56:48', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0856158-ec98-4db3-8070-3e1a7b55ff79'	System	23 Aug 2020 14:57:01
User entered 'None (0)'	System	23 Aug 2020 14:57:01

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:56:53', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0856158-ec98-4db3-8070-3e1a7b55ff79'	System	23 Aug 2020 14:57:01
User entered 'No (N)'	System	23 Aug 2020 14:57:01

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T10:56:58', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'd0856158-ec98-4db3-8070-3e1a7b55ff79'	System	23 Aug 2020 14:57:01
User entered '23 Aug 2020 10:56'	System	23 Aug 2020 14:57:01

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Aug 2020 14:57:01
User entered 'Day 8'	System	23 Aug 2020 14:57:01

US3402382

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T23:15:09', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2459a4e8-c5d5-48b9-bc96-e8aabcbf5072'	System	24 Aug 2020 03:15:24
User entered 'No interference with activity (1)'	System	24 Aug 2020 03:15:24

US3402382

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:28:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T23:15:20', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '2459a4e8-c5d5-48b9-bc96-e8aabcbf5072'	System	24 Aug 2020 03:15:24
User entered '23 Aug 2020 23:15'	System	24 Aug 2020 03:15:24

US3402382

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	23 Aug 2020 14:57:01

US3402382

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	23 Aug 2020 14:57:01

US3402382

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Aug 2020 14:57:01
User entered 'Day 9'	System	23 Aug 2020 14:57:01

US3402382

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-24T19:22:27', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '8e9111dc-4ad6-4932-855d-938f406bb53f'	System	24 Aug 2020 23:22:34
User entered 'None (0)'	System	24 Aug 2020 23:22:34

US3402382

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:28:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-24T19:22:32', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '8e9111dc-4ad6-4932-855d-938f406bb53f' User entered '24 Aug 2020 19:22'	System	24 Aug 2020 23:22:34
	System	24 Aug 2020 23:22:34

US3402382

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 14:57:01

US3402382

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 14:57:01

US3402382

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Aug 2020 14:57:01
User entered 'Day 8'	System	23 Aug 2020 14:57:01

US3402382

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T23:15:27', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '9dc854a7-2197-4b1c-b455-909796aff921'	System	24 Aug 2020 03:15:37
User entered 'No (N)'	System	24 Aug 2020 03:15:37

US3402382

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-23T23:15:34', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '9dc854a7-2197-4b1c-b455-909796aff921'	System	24 Aug 2020 03:15:37
User entered '23 Aug 2020 23:15'	System	24 Aug 2020 03:15:37

US3402382

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	23 Aug 2020 14:57:01

US3402382

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	23 Aug 2020 14:57:01

US3402382

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Aug 2020 14:57:01
User entered 'Day 9'	System	23 Aug 2020 14:57:01

US3402382

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-24T19:22:41', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '088a4cdb-b744-4251-a17f-1853bb558181'	System	24 Aug 2020 23:22:50
User entered 'No (N)'	System	24 Aug 2020 23:22:50

US3402382

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:28:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-08-24T19:22:47', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '088a4cdb-b744-4251-a17f-1853bb558181'	System	24 Aug 2020 23:22:50
User entered '24 Aug 2020 19:22'	System	24 Aug 2020 23:22:50

US3402382

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 14:57:01

US3402382

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 14:57:01

US3402382

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	24 Aug 2020 20:07:53

US3402382

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	24 Aug 2020 20:07:53

US3402382

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4)	24 Aug 2020 20:07:53
	(b) (4)	

US3402382

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	24 Aug 2020 20:07:53
	(b) (4)	

US3402382

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	24 Aug 2020 20:07:57
	(b) (4)	

US3402382

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 20:07:57

US3402382

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:28

US3402382

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

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).	(b) (4), (b) (6)	11 Sep 2020 13:04:27
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.'	Traci Hull (b) (4)	10 Sep 2020 13:15:40
answered with 'date correct' (Site from System).	(b) (4)	
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	10 Sep 2020 13:15:28
User entered '16 Aug 2020'	Traci Hull (b) (4)	10 Sep 2020 13:15:28
	(b) (4)	

US3402382

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:28

US3402382

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:28

US3402382

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:47

US3402382

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 13:15:47

US3402382

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:16:04

US3402382

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:31:50
User entered '6 Sep 2020'	Traci Hull (b) (4)	10 Sep 2020 13:16:04

US3402382

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:16:04

US3402382

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:16:04

US3402382

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:16:10

US3402382

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 13:16:10

US3402382

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:50

US3402382

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:50

US3402382

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:50

US3402382

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	14 Sep 2020 17:15:50

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '11:30'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:30'	System	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.3' C	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '64'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '18'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '136'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 08:12:42
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NO CS/NCS THIS IS THE SUBJECTS CORRECT DIASTOLIC BLOOD PRESSURE' (Site from System).	Tammy Kohn (b) (4)	18 Sep 2020 13:37:07
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:59:08
User entered '58'	Traci Hull (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:28:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '12:35'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:35'	System	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.4' C	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '52'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '18'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '130'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '62'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:28:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Sep 2020 17:18:17

US3402382

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:23

US3402382

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:23

US3402382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	14 Sep 2020 16:12:18

US3402382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	14 Sep 2020 16:12:18

US3402382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	14 Sep 2020 16:12:18

US3402382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 16:12:18

US3402382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Tarin Gordon (b) (4) (b) (4)	14 Sep 2020 16:12:18

US3402382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '12:03'	Tarin Gordon (b) (4) (b) (4)	14 Sep 2020 16:12:18

US3402382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:03'	System	14 Sep 2020 16:12:18

US3402382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Tarin Gordon (b) (4) (b) (4)	14 Sep 2020 16:12:18

US3402382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	14 Sep 2020 16:12:18

US3402382

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 16:12:18

US3402382

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Per IMMUNO Lab Recon: GCL has a Unscheduled Lab with a collection date of 28AUG2020; however, there is no record in EDC with this date. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 17:47:00
Query 'Per IMMUNO Lab Recon: GCL has a Unscheduled Lab with a collection date of 28AUG2020; however, there is no record in EDC with this date. Please reconcile or clarify.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	06 Oct 2020 17:34:13
User opened query 'Per IMMUNO Lab Recon: GCL has a Unscheduled Lab with a collection date of 28AUG2020; however, there is no record in EDC with this date. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 08:52:07
User entered 'Yes (Y)'	Traci Hull (b) (4)	14 Sep 2020 17:18:44

US3402382

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:44

US3402382

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '11:46'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:44

US3402382

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:46'	System	14 Sep 2020 17:18:44

US3402382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:28:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab: response noted. However, please confirm if unscheduled lab kit was used for visit 2 day 29. since both visits have the same collection date.' answered with 'VISIT 2 DAY 29 KIT A WOULD HAVE BEEN USED NOT UNSCHEDULED.' (Site from DM).	Traci Hull (b) (4) (b) (4)	04 Nov 2020 15:10:14
User opened query 'Per GCL Lab Reconciliation: Swab: response noted. However, please confirm if unscheduled lab kit was used for visit 2 day 29. since both visits have the same collection date.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 14:48:45
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 14SEP2020 is reported under Unscheduled visit in PPD Central lab, however same date is reported under Visit 2 Day 29 in EDC. Please confirm the correct visit. else clarify' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 14:48:45
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 14SEP2020 is reported under Unscheduled visit in PPD Central lab, however same date is reported under Visit 2 Day 29 in EDC. Please confirm the correct visit. else clarify' answered with 'This is correct as is' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 14:00:55
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 14SEP2020 is reported under Unscheduled visit in PPD Central lab, however same date is reported under Visit 2 Day 29 in EDC. Please confirm the correct visit. else clarify' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:44:31
User entered '14 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:56

US3402382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:09

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:56

US3402382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:56

US3402382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '11:43'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:56

US3402382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:43'	System	14 Sep 2020 17:18:56

US3402382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:09

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:56

US3402382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:56

US3402382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:18:56

US3402382

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 17:18:56

US3402382

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:19:00

US3402382

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 17:19:00

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:35:45', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7204a7b9-2912-48fc-abdc-d2fee24c0577'	System	14 Sep 2020 16:35:58
User entered 'Yes (Y)'	System	14 Sep 2020 16:35:58

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:35:30', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7204a7b9-2912-48fc-abdc-d2fee24c0577'	System	14 Sep 2020 16:35:58
User entered '97.4'	System	14 Sep 2020 16:35:58

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:35:38', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7204a7b9-2912-48fc-abdc-d2fee24c0577'	System	14 Sep 2020 16:35:58
User entered 'No (N)'	System	14 Sep 2020 16:35:58

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:35:55', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '7204a7b9-2912-48fc-abdc-d2fee24c0577'	System	14 Sep 2020 16:35:58
User entered '14 Sep 2020 12:35'	System	14 Sep 2020 16:35:58

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:23'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 14:53'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 15:48'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 2'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 3'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 4'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 5'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 6'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 7'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:36:08', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c2729988-399e-4bc0-ab9a-6c1ffddb3c0'	System	14 Sep 2020 16:36:44
User entered 'None (1)'	System	14 Sep 2020 16:36:44

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:36:12', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c2729988-399e-4bc0-ab9a-6c1ffddb3c0'	System	14 Sep 2020 16:36:44
User entered 'No (N)'	System	14 Sep 2020 16:36:44

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:36:23', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c2729988-399e-4bc0-ab9a-6c1ffddb3c0'	System	14 Sep 2020 16:36:44
User entered 'No (N)'	System	14 Sep 2020 16:36:44

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:36:30', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c2729988-399e-4bc0-ab9a-6c1ffddb3c0'	System	14 Sep 2020 16:36:44
User entered 'None (1)'	System	14 Sep 2020 16:36:44

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:36:40', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'c2729988-399e-4bc0-ab9a-6c1ffddb3c0'	System	14 Sep 2020 16:36:44
User entered '14 Sep 2020 12:36'	System	14 Sep 2020 16:36:44

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:23'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 14:53'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 15:48'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 2'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 3'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 4'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 5'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 6'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 7'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:36:54', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'b0889c7b-c5d6-4321-8651-b7cbf1261355'	System	14 Sep 2020 16:37:44
User entered 'None (0)'	System	14 Sep 2020 16:37:44

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:37:03', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'b0889c7b-c5d6-4321-8651-b7cbf1261355'	System	14 Sep 2020 16:37:44
User entered 'No interference with activity (1)'	System	14 Sep 2020 16:37:44

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:37:09', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'b0889c7b-c5d6-4321-8651-b7cbf1261355'	System	14 Sep 2020 16:37:44
User entered 'None (0)'	System	14 Sep 2020 16:37:44

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:37:15', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'b0889c7b-c5d6-4321-8651-b7cbf1261355'	System	14 Sep 2020 16:37:44
User entered 'None (0)'	System	14 Sep 2020 16:37:44

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:37:20', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'b0889c7b-c5d6-4321-8651-b7cbf1261355'	System	14 Sep 2020 16:37:44
User entered 'None (0)'	System	14 Sep 2020 16:37:44

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:37:24', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'b0889c7b-c5d6-4321-8651-b7cbf1261355'	System	14 Sep 2020 16:37:44
User entered 'None (0)'	System	14 Sep 2020 16:37:44

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

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 (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:37:36', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'b0889c7b-c5d6-4321-8651-b7cbf1261355'	System	14 Sep 2020 16:37:44
User entered 'No (N)'	System	14 Sep 2020 16:37:44

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-09-14T12:37:40', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'b0889c7b-c5d6-4321-8651-b7cbf1261355'	System	14 Sep 2020 16:37:44
User entered '14 Sep 2020 12:37'	System	14 Sep 2020 16:37:44

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:23'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 14:53'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 15:48'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 2'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 3'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 4'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 5'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 6'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Sep 2020 16:12:18
User entered 'Day 7'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:12:18

US3402382

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:28:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:12:18

US3402382

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	21 Sep 2020 18:35:31

US3402382

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Traci Hull (b) (4) (b) (4)	21 Sep 2020 18:35:31

US3402382

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	21 Sep 2020 18:35:31

US3402382

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	21 Sep 2020 18:35:31

US3402382

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	21 Sep 2020 18:35:36

US3402382

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 18:35:36

US3402382

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Sep 2020 19:52:31

US3402382

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Traci Hull (b) (4) (b) (4)	29 Sep 2020 19:52:31

US3402382

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	29 Sep 2020 19:52:31

US3402382

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	29 Sep 2020 19:52:31

US3402382

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Sep 2020 19:52:35

US3402382

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 19:52:35

US3402382

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:31:19

US3402382

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:32:46
User entered '5 Oct 2020'	Traci Hull (b) (4)	12 Oct 2020 17:31:19

US3402382

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:31:19

US3402382

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:31:19

US3402382

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:31:23

US3402382

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 17:31:23

US3402382

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:31:34

US3402382

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:31:34

US3402382

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:31:34

US3402382

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	12 Oct 2020 17:31:34

US3402382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

US3402382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

US3402382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '12:32'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

US3402382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:32'	System	12 Oct 2020 17:32:11

US3402382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.1' F	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

US3402382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

US3402382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

US3402382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '63'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

US3402382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Oct 2020 17:32:11

US3402382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '16'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

US3402382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Oct 2020 17:32:11

US3402382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '108'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

US3402382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 17:32:11

US3402382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '75'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:11

US3402382

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Oct 2020 17:32:11

US3402382

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:19

US3402382

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:19

US3402382

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:31

US3402382

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:31

US3402382

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '12:35'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:31

US3402382

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:35'	System	12 Oct 2020 17:32:31

US3402382

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 17:32:36

US3402382

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 17:32:36

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 64'	System	16 Aug 2020 17:17:49

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-16T08:25:10', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '29ff1126-e938-4b91-b767-549b43fbf1fe' User entered 'No (N)'	System	16 Oct 2020 12:25:37

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-16T08:25:16', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '29ff1126-e938-4b91-b767-549b43fbf1fe' User entered 'No (N)'	System	16 Oct 2020 12:25:37

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-16T08:25:33', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '29ff1126-e938-4b91-b767-549b43fbf1fe' User entered '16 Oct 2020 08:25:33'	System	16 Oct 2020 12:25:37
	System	16 Oct 2020 12:25:37

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered '16 Oct 2020 00:01'	System	16 Aug 2020 17:17:49

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered '20 Oct 2020 23:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 71'	System	16 Aug 2020 17:17:49

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-23T11:08:23', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1599dade-793a-4dee-b434-0bac5787adc7' User entered 'No (N)'	System	23 Oct 2020 15:08:43
	System	23 Oct 2020 15:08:43

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-23T11:08:30', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1599dade-793a-4dee-b434-0bac5787adc7' User entered 'No (N)'	System	23 Oct 2020 15:08:43

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-23T11:08:41', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '1599dade-793a-4dee-b434-0bac5787adc7' User entered '23 Oct 2020 11:08:41'	System	23 Oct 2020 15:08:43
	System	23 Oct 2020 15:08:43

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered '23 Oct 2020 00:01'	System	16 Aug 2020 17:17:49

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered '27 Oct 2020 23:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered 'Day 78'	System	16 Aug 2020 17:17:49

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-31T11:06:27', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '336840dd-3748-443d-bf46-a3643e70a549' User entered 'Yes (Y)'	System	31 Oct 2020 15:07:39
	System	31 Oct 2020 15:07:39

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-31T11:06:34', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '336840dd-3748-443d-bf46-a3643e70a549'	System	31 Oct 2020 15:07:39
User entered 'No (N)'	System	31 Oct 2020 15:07:39

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-31T11:06:46', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '336840dd-3748-443d-bf46-a3643e70a549'	System	31 Oct 2020 15:07:39
User entered 'No (N)'	System	31 Oct 2020 15:07:39

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-31T11:06:55', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '336840dd-3748-443d-bf46-a3643e70a549' User entered 'Yes (Y)'	System	31 Oct 2020 15:07:39
	System	31 Oct 2020 15:07:39

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-31T11:07:17', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '336840dd-3748-443d-bf46-a3643e70a549'	System	31 Oct 2020 15:07:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Oct 2020 15:07:39

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-10-31T11:07:29', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '336840dd-3748-443d-bf46-a3643e70a549' User entered '31 Oct 2020 11:07:29'	System	31 Oct 2020 15:07:39
	System	31 Oct 2020 15:07:39

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered '30 Oct 2020 00:01'	System	16 Aug 2020 17:17:49

US3402382

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 17:17:49
User entered '03 Nov 2020 23:59'	System	16 Aug 2020 17:17:49

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '13 Oct 2020 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '17 Oct 2020 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '20 Oct 2020 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '24 Oct 2020 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '27 Oct 2020 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '31 Oct 2020 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '03 Nov 2020 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '07 Nov 2020 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '10 Nov 2020 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '14 Nov 2020 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-11-19T12:20:30', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '27d97114-8583-4367-95c6-f5e6f3791bd8'	System	19 Nov 2020 17:20:45
User entered 'No (N)'	System	19 Nov 2020 17:20:45

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-11-19T12:20:34', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '27d97114-8583-4367-95c6-f5e6f3791bd8'	System	19 Nov 2020 17:20:45
User entered 'No (N)'	System	19 Nov 2020 17:20:45

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-11-19T12:20:42', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: '27d97114-8583-4367-95c6-f5e6f3791bd8' User entered '19 Nov 2020 12:20:42'	System	19 Nov 2020 17:20:45
	System	19 Nov 2020 17:20:45

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '17 Nov 2020 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '21 Nov 2020 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-11-24T07:50:36', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'bfa4db36-22f9-454e-a66e-29498ff42a45'	System	24 Nov 2020 12:51:08
User entered 'No (N)'	System	24 Nov 2020 12:51:08

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-11-24T07:50:55', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'bfa4db36-22f9-454e-a66e-29498ff42a45'	System	24 Nov 2020 12:51:08
User entered 'No (N)'	System	24 Nov 2020 12:51:08

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FE7DF7B9-2794-4D16-AD33-78D387336522)', Time: '2020-11-24T07:51:05', User OID: 'PatientReportedOutcome (US3402382)', ODM File OID: 'bfa4db36-22f9-454e-a66e-29498ff42a45'	System	24 Nov 2020 12:51:08
User entered '24 Nov 2020 07:51:05'	System	24 Nov 2020 12:51:08

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '24 Nov 2020 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '28 Nov 2020 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '01 Dec 2020 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '05 Dec 2020 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '08 Dec 2020 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '12 Dec 2020 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '15 Dec 2020 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '19 Dec 2020 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '22 Dec 2020 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '26 Dec 2020 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '29 Dec 2020 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '02 Jan 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '05 Jan 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '09 Jan 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '12 Jan 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '16 Jan 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '19 Jan 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '23 Jan 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '26 Jan 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '30 Jan 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '02 Feb 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '06 Feb 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '09 Feb 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '13 Feb 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '16 Feb 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '20 Feb 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '23 Feb 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '27 Feb 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '02 Mar 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '06 Mar 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '09 Mar 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '13 Mar 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '16 Mar 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '20 Mar 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '23 Mar 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '27 Mar 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '30 Mar 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '03 Apr 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '06 Apr 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '10 Apr 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '13 Apr 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '17 Apr 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '20 Apr 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '24 Apr 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '27 Apr 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '01 May 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '04 May 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '08 May 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '11 May 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '15 May 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '18 May 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '22 May 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '25 May 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '29 May 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '01 Jun 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '05 Jun 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '08 Jun 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '12 Jun 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '15 Jun 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '19 Jun 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '22 Jun 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '26 Jun 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '29 Jun 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '03 Jul 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '06 Jul 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '10 Jul 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '13 Jul 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '17 Jul 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '20 Jul 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '24 Jul 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '27 Jul 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '31 Jul 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '03 Aug 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '07 Aug 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '10 Aug 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '14 Aug 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '17 Aug 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '21 Aug 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '24 Aug 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '28 Aug 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '31 Aug 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '04 Sep 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '07 Sep 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '11 Sep 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '14 Sep 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '18 Sep 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '21 Sep 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '25 Sep 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '28 Sep 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '02 Oct 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '05 Oct 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '09 Oct 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '12 Oct 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '16 Oct 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '19 Oct 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '23 Oct 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '26 Oct 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '30 Oct 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '02 Nov 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '06 Nov 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '09 Nov 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '13 Nov 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '16 Nov 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '20 Nov 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '23 Nov 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '27 Nov 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '30 Nov 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '04 Dec 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '07 Dec 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '11 Dec 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '14 Dec 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '18 Dec 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '21 Dec 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '25 Dec 2021 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '28 Dec 2021 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '01 Jan 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '04 Jan 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '08 Jan 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '11 Jan 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '15 Jan 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '18 Jan 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '22 Jan 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '25 Jan 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '29 Jan 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '01 Feb 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '05 Feb 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '08 Feb 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '12 Feb 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '15 Feb 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '19 Feb 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '22 Feb 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '26 Feb 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '01 Mar 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '05 Mar 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '08 Mar 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '12 Mar 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '15 Mar 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '19 Mar 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '22 Mar 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '26 Mar 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '29 Mar 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '02 Apr 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '05 Apr 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '09 Apr 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '12 Apr 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '16 Apr 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '19 Apr 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '23 Apr 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '26 Apr 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '30 Apr 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 08:46:29

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '03 May 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '07 May 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '10 May 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '14 May 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '17 May 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '21 May 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '24 May 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '28 May 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '31 May 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '04 Jun 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 08:46:29

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '07 Jun 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '11 Jun 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '14 Jun 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '18 Jun 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '21 Jun 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '25 Jun 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '28 Jun 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '02 Jul 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '05 Jul 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '09 Jul 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '12 Jul 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '16 Jul 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '19 Jul 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '23 Jul 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '26 Jul 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '30 Jul 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '02 Aug 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '06 Aug 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '09 Aug 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '13 Aug 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '16 Aug 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '20 Aug 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '23 Aug 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '27 Aug 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '30 Aug 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '03 Sep 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '06 Sep 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '10 Sep 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '13 Sep 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '17 Sep 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '20 Sep 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '24 Sep 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '27 Sep 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '01 Oct 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '04 Oct 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '08 Oct 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '11 Oct 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '15 Oct 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '18 Oct 2022 00:01'	System	19 Nov 2020 08:46:29

US3402382

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:28:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:46:29
Amendment Manager: User entered '22 Oct 2022 23:59'	System	19 Nov 2020 08:46:29

US3402382

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	09 Nov 2020 19:27:55

US3402382

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:33:31
User entered '9 Nov 2020'	Tammy Kohn (b) (4)	09 Nov 2020 19:27:55

US3402382

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	09 Nov 2020 19:27:55

US3402382

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:28:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	09 Nov 2020 19:27:55

US3402382

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	09 Nov 2020 19:27:58

US3402382

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:28:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 19:27:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:09

[Date of Contact](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: It appears subject reported symptoms; however, COVID Diagnostic Test form is not completed. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:41:16
Query 'Per CDM: It appears subject reported symptoms; however, COVID Diagnostic Test form is not completed. Please reconcile.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	05 Oct 2020 13:30:07
User entered '26 Aug 2020' reason for change: Data Entry Error	(b) (4)	05 Oct 2020 13:30:01
User opened query 'Per CDM: It appears subject reported symptoms; however, COVID Diagnostic Test form is not completed. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 08:48:55
User entered '25 Aug 2020'	Traci Hull (b) (4)	04 Sep 2020 12:40:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:09

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '07:00'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 12:40:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:09

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 07:00'	System	05 Oct 2020 13:30:01
User entered '25 Aug 2020 07:00'	System	04 Sep 2020 12:40:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:09

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 12:40:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:28:09

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 12:40:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[Date](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[Temperature](#)

Audit	User	Time (GMT)
User entered '99.5' F	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:28:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:55:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[Date](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.2' F	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:28:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:56:03

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[Date](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[Temperature](#)

Audit	User	Time (GMT)
User entered '96.8' F	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:28:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:57:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[Date](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:28:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:10

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[Date](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:28:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:58:57

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[Date](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:28:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:59:34

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[Date](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:57:16
User entered '1 Sep 2020'	Traci Hull (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:28:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Not Done (Not Done)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:00:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[Date](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:57:16
User entered '2 Sep 2020'	Traci Hull (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.8' F	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:28:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[Date](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:57:16
User entered '3 Sep 2020'	Traci Hull (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '96'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[Temperature](#)

Audit	User	Time (GMT)
User entered '36.1' C	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:28:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 14:01:46

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[Date](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:57:16
User entered '4 Sep 2020'	Traci Hull (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[Temperature](#)

Audit	User	Time (GMT)
User entered '96.4' F	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:28:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:10:04

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[Date](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:58:06
User entered '5 Sep 2020'	Traci Hull (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[Temperature](#)

Audit	User	Time (GMT)
User entered '96.0' F	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:28:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:11:01

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[Date](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:58:06
User entered '6 Sep 2020'	Traci Hull (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[Temperature](#)

Audit	User	Time (GMT)
User entered '96.9' F	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:28:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:13:23

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[Date](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:58:06
User entered '7 Sep 2020'	Traci Hull (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[Temperature](#)

Audit	User	Time (GMT)
User entered '36.4' C	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:28:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:14:11

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[Date](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:58:06
User entered '8 Sep 2020'	Traci Hull (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[Temperature](#)

Audit	User	Time (GMT)
User entered '96.4' F	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:28:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 13:15:00

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[Date](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:58:06
User entered '9 Sep 2020'	Traci Hull (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[Temperature](#)

Audit	User	Time (GMT)
User entered '96.9' F	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:28:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:36:51

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[Date](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '95'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.9' F	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:28:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 20:37:27

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 17 (Day 17)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[Date](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.6' F	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:28:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 17:15:22

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 18 (Day 18)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[Date](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.4' F	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:28:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:50:58

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 19 (Day 19)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[Date](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.7' F	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:28:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:51:39

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:09

[Date of Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 28 AUG 2020 is reported under UNSCHEDULED Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:59:04
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 28 AUG 2020 is reported under UNSCHEDULED Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Sample was collected 28Aug2020 ' (Site from DM).	Jennifer Molstead (b) (4)	30 Oct 2020 14:04:00
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 28 AUG 2020 is reported under UNSCHEDULED Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:20:06
User entered '26 Aug 2020'	Tammy Kohn (b) (4)	05 Oct 2020 12:13:44

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:09

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 12:13:44

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:09

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 12:13:44

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:09

[Date of Test](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 12:13:44

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:09

[Type of Test Performed](#)

Audit	User	Time (GMT)
User entered 'Nasal Swab (Nasal Swab)'	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 12:13:44

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:09

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 12:13:44

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:09

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User closed query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	05 Oct 2020 12:14:17
User opened query 'Was this diagnostic test performed at a lab other than the Study Central Lab? is No, however, Lab/ Institution Test Performed and/or CLIA Certified? is provided. Please review and reconcile.' (Site from System).	System	05 Oct 2020 12:13:55
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	05 Oct 2020 12:13:55
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	05 Oct 2020 12:13:44

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:09

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Oct 2020 12:13:55
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Oct 2020 12:13:44
User entered empty.	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 12:13:44

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:09

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	05 Oct 2020 12:14:17
User entered 'No (N)'	Tammy Kohn (b) (4)	05 Oct 2020 12:13:44

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:28:09

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Oct 2020 12:13:44

US3402382

Folder: Covid-19 Assessment 26 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:28:09

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	05 Oct 2020 12:14:29

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:28:09

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:28:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:28:09

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 28AUG2020, 01SEP2020 and 08SEP2020 for Day 3, Day 7 and Day 14 is recorded in EDC central lab, however same is reported with 31AUG2020, 03SEP2020 and 09SEP2020 for Day 3, Day 7 and Day 14 in PPD Central lab. Please reconcile and update if applicable, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 06:51:49
Query 'Per GCL Lab Recon: Saliva: Sample dated 28AUG2020, 01SEP2020 and 08SEP2020 for Day 3, Day 7 and Day 14 is recorded in EDC central lab, however same is reported with 31AUG2020, 03SEP2020 and 09SEP2020 for Day 3, Day 7 and Day 14 in PPD Central lab. Please reconcile and update if applicable, else clarify. Thank you.' answered with 'Dates in EDC are correct' (Site from DM).	Jennifer Molstead (b) (4)	30 Oct 2020 12:42:58
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 28AUG2020, 01SEP2020 and 08SEP2020 for Day 3, Day 7 and Day 14 is recorded in EDC central lab, however same is reported with 31AUG2020, 03SEP2020 and 09SEP2020 for Day 3, Day 7 and Day 14 in PPD Central lab. Please reconcile and update if applicable, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:52:32
User entered '28 Aug 2020'	Traci Hull (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:28:09

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 31AUG2020 and 09SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:42:05
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 31AUG2020 and 09SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'NO SAMPLE DONE AS PATIENT WAS IN THE HOSPITAL' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	19 Nov 2020 13:41:47
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 31AUG2020 and 09SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 05:10:49
User accepted default value 'Day 5 (Day 5)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:28:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:28:09

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty; reason for change New Information	Jennifer Molstead (b) (4)	(b) (4) 24 Nov 2020 17:52:16
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31AUG2020 and 09SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' answered with 'SUBJECT DID NOT COLLECT THIS SAMPLE' (Site from DM).	Jennifer Molstead (b) (4)	(b) (4) 24 Nov 2020 17:51:59
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 31AUG2020 and 09SEP2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:42:19
User entered '30 Aug 2020'	Traci Hull (b) (4)	(b) (4) 27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:28:09

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:28:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:28:09

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty; reason for change New Information	Jennifer Molstead (b) (4)	24 Nov 2020 17:52:37
User entered '01 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:58:54
User entered '1 Sep 2020'	Traci Hull (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:28:09

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:28:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:28:09

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:58:54
User entered '3 Sep 2020'	Traci Hull (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:28:09

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:28:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:28:09

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 13:58:54
User entered '8 Sep 2020'	Traci Hull (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:28:09

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:28:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 14:23:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 14:23:36
User entered 'No (N)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:23:36
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 11:44:15
User entered empty.	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:28:09

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty; reason for change New Information	Jennifer Molstead (b) (4)	24 Nov 2020 17:53:09
User entered '27 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	27 Oct 2020 14:23:36
User entered empty.	Traci Hull (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:28:09

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:28:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 14:23:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 14:23:36
User entered 'No (N)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	27 Oct 2020 14:23:36
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 11:44:15
User entered empty.	Traci Hull (b) (4) (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:28:09

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty; reason for change New Information	Jennifer Molstead (b) (4)	24 Nov 2020 17:53:09
User entered '27 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	27 Oct 2020 14:23:36
User entered empty.	Traci Hull (b) (4)	27 Oct 2020 11:44:15

US3402382

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 28 AUG 2020 is reported under UNSCHEDULED Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:19:55
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 28 AUG 2020 is reported under UNSCHEDULED Visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:19:30
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:17:20

US3402382

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:17:20

US3402382

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:17:20

US3402382

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:28:09

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	26 Aug 2020 19:17:20

US3402382

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:12

US3402382

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:12

US3402382

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '12:51'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:12

US3402382

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:51'	System	26 Aug 2020 19:19:12

US3402382

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '187.9' cm	Traci Hull (b) (4)	26 Aug 2020 19:19:12
DataPoint set to visible.	(b) (4) System	26 Aug 2020 19:17:20

US3402382

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '127.9' kg	Traci Hull (b) (4)	26 Aug 2020 19:19:12
DataPoint set to visible.	(b) (4) System	26 Aug 2020 19:17:20

US3402382

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '99.5' F	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:12

US3402382

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:12

US3402382

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:12

US3402382

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per previous query, please confirm if this value should be considered NCS or not.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 12:24:36
Query 'Per CDM: Per previous query, please confirm if this value should be considered NCS or not.' answered with 'This was considered clinically significant. Patient was advised to go to the Emergency Room. Patient declined' (Site from DM).	Jennifer Molstead (b) (4)	16 Sep 2020 17:07:56
User opened query 'Per CDM: Per previous query, please confirm if this value should be considered NCS or not.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 10:43:48
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 10:43:20
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'CORRECT AS IS' (Site from System).	Jennifer Molstead (b) (4)	14 Sep 2020 01:42:34
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	26 Aug 2020 19:19:12
User entered '137'	Traci Hull (b) (4)	26 Aug 2020 19:19:12

US3402382

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Aug 2020 19:19:12

US3402382

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '16'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:12

US3402382

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Aug 2020 19:19:12

US3402382

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '120'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:12

US3402382

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Aug 2020 19:19:12

US3402382

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '86'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:12

US3402382

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:28:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Aug 2020 19:19:12

US3402382

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:33

US3402382

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:28:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 19:19:33

US3402382

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:28:09

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: GCL has Saliva Day 3, Day 7, and Day 14 with dates of 31AUG2020, 03SEP2020, and 09SEP2020 respectively; however there is no Saliva Log completed. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 09:50:12
Query 'Per GCL Lab Recon: GCL has Saliva Day 3, Day 7, and Day 14 with dates of 31AUG2020, 03SEP2020, and 09SEP2020 respectively; however there is no Saliva Log completed. Please reconcile or clarify' answered with 'Log has been updated' (Site from DM).	Jennifer Molstead (b) (4)	30 Oct 2020 14:02:23
User opened query 'Per GCL Lab Recon: GCL has Saliva Day 3, Day 7, and Day 14 with dates of 31AUG2020, 03SEP2020, and 09SEP2020 respectively; however there is no Saliva Log completed. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 20:56:47
User entered 'Yes (Y)'	Traci Hull (b) (4)	26 Aug 2020 19:20:38

US3402382

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:28:09

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 AUG 2020 is reported under illness visit Day 1 in EDC, however the same is reported in the UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 12:01:42
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 AUG 2020 is reported under illness visit Day 1 in EDC, however the same is reported in the UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' answered with 'DATA HAS BEEN SET TO PPD TO UPDATE THE INFORMATION TO ILLNESS VISIT.' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	11 Nov 2020 17:05:26
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 28 AUG 2020 is reported under illness visit Day 1 in EDC, however the same is reported in the UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 05:54:30
User entered '28 Aug 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 14:03:22
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 26 AUG 2020 is reported under illness Visit in EDC, however the Sample dated 28 AUG 2020 is recorded under illness visit in PPD Central lab. Please confirm the correct Visit date and update if applicable. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:17:46
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 26 AUG 2020 is reported under illness Visit in EDC, however the Sample dated 28 AUG 2020 is recorded under illness visit in PPD Central lab. Please confirm the correct Visit date and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:14:08

US3402382

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:28:09

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4)	06 Oct 2020 17:09:10
User entered '28 Aug 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4)	05 Oct 2020 17:59:45
User entered '26 Aug 2020'	Traci Hull (b) (4)	26 Aug 2020 19:20:38

US3402382

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:28:09

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:58:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	02 Sep 2020 10:27:17
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 12:03:38

US3402382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:41
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 21:56:41
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:11:38
User entered	System	02 Sep 2020 13:11:09
'USA-US059-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	02 Sep 2020 13:11:09

US3402382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:25
User closed query 'Per AE log, Atrial Fibrillation was the AE. Please review and update eCRF or AE Log.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:47:19
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4)	07 Nov 2020 15:05:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Nov 2020 15:05:33
Data point term sent to Coder	System	07 Nov 2020 15:04:58
Query 'Per AE log, Atrial Fibrillation was the AE. Please review and update eCRF or AE Log.' answered with 'Updated' (Site from CRA).	Jennifer Molstead (b) (4)	07 Nov 2020 15:04:32
DataPoint Un-verified.	Jennifer Molstead (b) (4)	07 Nov 2020 15:04:22
Coding entries removed.	Jennifer Molstead (b) (4)	07 Nov 2020 15:04:22
User entered 'ATRIAL Fibrillation' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 15:04:22
User opened query 'Per AE log, Atrial Fibrillation was the AE. Please review and update eCRF or AE Log.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 21:57:36
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User closed query 'PV Query: Please confirm if the fall met criteria for separate AE reporting.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:25:24
Query 'PV Query: Please confirm if the fall met criteria for separate AE reporting.' answered with 'It did not' (Site from Safety).	Jennifer Molstead (b) (4)	14 Sep 2020 01:30:53
User opened query 'PV Query: Please confirm if the fall met criteria for separate AE reporting.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:46:13
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial flutter, LLT: Atrial flutter - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 11:03:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 11:03:41

US3402382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	02 Sep 2020 11:02:51
User entered 'Atrial Flutter'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'No (N)'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User closed query 'PV Query: On 26 Aug 2020, the subject's pulse was 139 at convalescent visit. Was the subject diagnosed with COVID-19? If yes, please consider reporting COVID-19 as an additional AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 17:20:54
Query 'PV Query: On 26 Aug 2020, the subject's pulse was 139 at convalescent visit. Was the subject diagnosed with COVID-19? If yes, please consider reporting COVID-19 as an additional AE/SAE.' answered with 'NO COVID TEST CAME BACK NEGATIVE, SAE ALREADY LOGGED' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 18:50:43
User opened query 'PV Query: On 26 Aug 2020, the subject's pulse was 139 at convalescent visit. Was the subject diagnosed with COVID-19? If yes, please consider reporting COVID-19 as an additional AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 17:22:08
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

US3402382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	16 Sep 2020 23:59:08
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	14 Sep 2020 16:12:18
User entered '28 Aug 2020'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	14 Sep 2020 01:33:58
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Sep 2020 01:33:58
User entered empty; reason for change Data Entry Error	Jennifer Molstead (b) (4)	14 Sep 2020 01:33:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 11:02:13
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	02 Sep 2020 11:02:13
User entered 'UN:UN' (non-conformant).	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13

US3402382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 01:33:58
User entered '28 Aug 2020 UN:UN' (non-conformant).	System	02 Sep 2020 11:02:13

US3402382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'No (N)'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '1 Sep 2020'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	14 Sep 2020 01:33:58
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Sep 2020 01:33:58
User entered empty; reason for change Data Entry Error	Jennifer Molstead (b) (4)	14 Sep 2020 01:33:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 11:02:13
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	02 Sep 2020 11:02:13
User entered 'UN:UN' (non-conformant).	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 01:33:58
User entered '1 Sep 2020 UN:UN' (non-conformant).	System	02 Sep 2020 11:02:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User closed query 'PV Query: As the event required hospitalization, please consider changing intensity to grade 3. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:25:41
Query 'PV Query: As the event required hospitalization, please consider changing intensity to grade 3. If not, please clarify.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	14 Sep 2020 01:34:15
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	14 Sep 2020 01:33:58
User opened query 'PV Query: As the event required hospitalization, please consider changing intensity to grade 3. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:42:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '1'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '28 Aug 2020'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '1 Sep 2020'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'No (N)'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered empty.	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13
	(b) (4)	

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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)	06 Nov 2020 21:55:43
User entered '0'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'None (NONE)'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
Query 'PV Query: Please add stop dates or tick ongoing for all concomitant medications.' canceled (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:28:19
User opened query 'PV Query: Please add stop dates or tick ongoing for all concomitant medications.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:41:48
User entered '1'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	30 Oct 2020 14:46:41
User closed query 'PV Query: Thank you for reporting that SAE was resolved since subject's heart rate was back to normal Please consider updating the outcome in the EDC to recovered/resolved (currently reported as recovered/resolved with sequelae).' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:03:35
Query 'PV Query: Thank you for reporting that SAE was resolved since subject's heart rate was back to normal Please consider updating the outcome in the EDC to recovered/resolved (currently reported as recovered/resolved with sequelae).' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	29 Oct 2020 21:33:56
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	29 Oct 2020 21:33:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	29 Oct 2020 21:33:27
User opened query 'PV Query: Thank you for reporting that SAE was resolved since subject's heart rate was back to normal Please consider updating the outcome in the EDC to recovered/resolved (currently reported as recovered/resolved with sequelae).' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:21:31
User closed query 'PV Query: "pending cardiologist follow-up" can't be considered as sequelae. If the subject was in a-fib at the time of hospital discharge, please consider updating outcome to ongoing.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 17:21:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: "pending cardiologist follow-up" can't be considered as sequelae. If the subject was in a-fib at the time of hospital discharge, please consider updating outcome to ongoing.' answered with 'SAE IS RESOLVED SINCE PATIENT'S HEART RATE IS BACK TO NORMAL. THE PATIENT WILL FOLLOW UP WITH A CARDIOLOGIST TO FIGURE OUT WHY THE EVEN IS HAPPENING' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 18:49:57
User opened query 'PV Query: "pending cardiologist follow-up" can't be considered as sequelae. If the subject was in a-fib at the time of hospital discharge, please consider updating outcome to ongoing.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 17:21:43
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Jennifer Molstead (b) (4) (b) (4)	02 Sep 2020 11:02:13

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Folder: Adverse Events

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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)	06 Nov 2020 21:55:43
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	30 Oct 2020 14:46:41
User entered 'Subject will follow up with cardiologist on an outpatient basis.'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:38
User closed query 'PV Query: Thank you for providing dates when COVID-19 test was done. However, the date was reported as Oct. Please confirm if the month was Oct or Aug since the event occurred in AUG. Please update as necessary. ' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 16:14:21
User closed query 'PV Query: Thank you for providing dates when EKG was done. However, the date was reported as Oct. Please confirm if the month is Oct or Aug since the event occurred in Aug. Please update as necessary. ' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 16:14:19
Query 'PV Query: Thank you for providing dates when COVID-19 test was done. However, the date was reported as Oct. Please confirm if the month was Oct or Aug since the event occurred in AUG. Please update as necessary. ' answered with 'Updated' (Site from Safety).	Jennifer Molstead (b) (4)	07 Nov 2020 15:04:44
Query 'PV Query: Thank you for providing dates when EKG was done. However, the date was reported as Oct. Please confirm if the month is Oct or Aug since the event occurred in Aug. Please update as necessary. ' answered with 'Updated' (Site from Safety).	Jennifer Molstead (b) (4)	07 Nov 2020 15:04:39

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User opened query 'PV Query: Thank you for providing dates when COVID-19 test was done. However, the date was reported as Oct. Please confirm if the month was Oct or Aug since the event occurred in AUG. Please update as necessary. ' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 16:42:22
User opened query 'PV Query: Thank you for providing dates when EKG was done. However, the date was reported as Oct. Please confirm if the month is Oct or Aug since the event occurred in Aug. Please update as necessary. ' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 16:42:05
User closed query 'PV Query: Please provide the date COVID-19 test was performed which resulted negative.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:03:42
User closed query 'PV Query: Please provide the date EKG done which showed atypical atrial flutter with variable blockage.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 14:03:39

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT PRESENTED IN OFFICE 26/AUG/2020 FOR A CONVALESCENT DAY 1 VISIT. HIS PULSE WAS NOTED TO BE 139. HE ALSO STATED THAT HE THOUGHT HE WAS HAVING SYMPTOMS OF AN URINARY INFECTION. HE WAS ADVISED TO GO TO THE EMERGENCY ROOM AT THAT POINT. WHICH HE DECLINED. HE WAS GIVEN LEVOFLOXACIN 500MG PO FOR 10 DAYS. WHEN HE CAME TO LEAVE HIS DAY 3 SALIVA SAMPLE2 28OCT2020 IT WAS NOTED THAT THE PATIENT WAS NOT ANY BETTER. PATIENT STATED THAT HE WAS UNSTEADY ON HIS FEET AND HAD FALLEN PRIOR TO COMING TO DROP OFF SAMPLE. IT WAS AGAIN RECOMMENDED THAT THE SUBJECT GO TO THE ER. WHICH HE DID.DUE TO SUBJECT FALLING HE HAD A CT OF THE HEAD AND BRAIN, THAT WERE NEGATIVE. ALSO A CHEST X-RAY THAT WAS NEGATIVE. SUBJECTS BLOOD PRESSURE IN THE ER WAS 86/70 HEART RATE 134 AND A RESP RATE OF 20. SUBJECT HAS VARIOUS LABS, OF NOTE WERE CRP 14, CO2 20, BUN 36, CREATININE 1.9. IT WAS THOUGHT THAT HE HAD UROSEPSIS AND WAS STARTED ON ROCEPHIN, WHILE AWAITING URINE AND BLOOD CULTURE RESULTS WHICH WERE NEGATIVE. SUBJECT WAS ADMITTED 28OCT2020 WITH A DIAGNOSIS OF ATRIAL FLUTTER. A CONULT WITH CARDIOLOGY WAS CONDUCTED, AND PATIENT WAS STARTED ON 5 MG ELIQUIS DAILY AND WILL FOLLOW UP ON AN OUT PATIENT BASIS. COVID 19 TEST PREFORMED 26OCT2020 WITH A NEGATIVE RESULT. Subjects Heart rate has returned to normal with the help of medication which is captures on the ConMed log.' reason for change: Per Query Resolution Query 'PV Query: Please provide the date COVID-19 test was performed which resulted negative.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	(b) (4) 30 Oct 2020 12:44:37

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the date EKG done which showed atypical atrial flutter with variable blockage.' answered with 'UPdated' (Site from Safety).	Jennifer Molstead (b) (4)	29 Oct 2020 21:34:02
User entered 'SUBJECT PRESENTED IN OFFICE 26/AUG/2020 FOR A CONVALESCENT DAY 1 VISIT. HIS PULSE WAS NOTED TO BE 139. HE ALSO STATED THAT HE THOUGHT HE WAS HAVING SYMPTOMS OF AN URINARY INFECTION. HE WAS ADVISED TO GO TO THE EMERGENCY ROOM AT THAT POINT. WHICH HE DECLINED. HE WAS GIVEN LEVOFLOXACIN 500MG PO FOR 10 DAYS. WHEN HE CAME TO LEAVE HIS DAY 3 SALIVA SAMPLE2 28OCT2020 IT WAS NOTED THAT THE PATIENT WAS NOT ANY BETTER. PATIENT STATED THAT HE WAS UNSTEADY ON HIS FEET AND HAD FALLEN PRIOR TO COMING TO DROP OFF SAMPLE. IT WAS AGAIN RECOMMENDED THAT THE SUBJECT GO TO THE ER. WHICH HE DID.DUE TO SUBJECT FALLING HE HAD A CT OF THE HEAD AND BRAIN, THAT WERE NEGATIVE. ALSO A CHEST X-RAY THAT WAS NEGATIVE. SUBJECTS BLOOD PRESSURE IN THE ER WAS 86/70 HEART RATE 134 AND A RESP RATE OF 20. SUBJECT HAS VARIOUS LABS, OF NOTE WERE CRP 14, CO2 20, BUN 36, CREATININE 1.9. IT WAS THOUGHT THAT HE HAD UROSEPSIS AND WAS STARTED ON ROCEPHIN, WHILE AWAITING URINE AND BLOOD CULTURE RESULTS WHICH WERE NEGATIVE. SUBJECT WAS ADMITTED 28OCT2020 WITH A DIAGNOSIS OF ATRIAL FLUTTER. A CONULT WITH CARDIOLOGY WAS CONDUCTED, AND PATIENT WAS STARTED ON 5 MG ELIQUIS DAILY AND WILL FOLLOW UP ON AN OUT PATIENT BASIS. Covid 19 Test Preformed 26OCT2020 with a negative result' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	29 Oct 2020 21:33:27

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the date COVID-19 test was performed which resulted negative.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:21:17
User opened query 'PV Query: Please provide the date EKG done which showed atypical atrial flutter with variable blockage.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:21:10
User closed query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 18:11:29
Query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 17:55:12
User opened query 'Per DM CLR: SAE Narrative contains medications and procedures. Please make sure that these information are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 08:31:52
User closed query 'PV Query: Please provide results of any diagnostic tests performed (i.e. EKG, echocardiogram, etc.).' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 17:21:09
Query 'PV Query: Please provide results of any diagnostic tests performed (i.e. EKG, echocardiogram, etc.).' answered with 'EKG DONE SHOWED ATYPICAL ATRIAL FLUTTER WITH VARIABLE BLOCKAGE' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	29 Sep 2020 18:30:41
User closed query 'Did the subject ever experience any arrhythmia or other cardiac event? Please provide a detailed cardiac history.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:29:16
User closed query 'PV Query: Please provide repeat vital signs at discharge.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:29:14
User closed query 'PV Query: Please provide the cardiologist assessment from the consultation.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:29:12
User closed query 'PV Query: Was the subject in normal sinus rhythm at discharge? If so, was this confirmed by EKG?' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:29:09

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Did the patient require any treatment for hypotension or antiarrhythmics, etc. for atrial flutter? If so, please add to concomitant medication eCRF.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:29:06
User closed query 'PV query: The subject was prescribed levofloxacin after UTI was suspected, but the cultures were done after next visit to the ER. Did the subject take levofloxacin tablets before the cultures?' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:29:03
User closed query 'PV query: Did the subject have fever before the event and after dose 1? If yes, what severity?' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:28:59
User closed query 'PV Query: The event was reported as resolved with sequelae. Please provide the sequelae.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:28:39
User closed query 'PV Query: Please confirm if an EKG was done on 26 Aug 2020, when the subject's heart rate was 136. If so, please provide results. If atrial flutter was confirmed on this date, please consider amending event start date.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:28:36
Query 'PV Query: Please provide the cardiologist assessment from the consultation.' answered with 'SUBJECT HAS NOT HAD APPOINTMENT YET' (Site from Safety).	Jennifer Molstead (b) (4)	(b) (4) 14 Sep 2020 01:38:32
Query 'Did the subject ever experience any arrhythmia or other cardiac event? Please provide a detailed cardiac history.' answered with 'INFORMATION NOT AVAILABLE' (Site from Safety).	Jennifer Molstead (b) (4)	(b) (4) 14 Sep 2020 01:37:52
Query 'PV Query: Please provide repeat vital signs at discharge.' answered with 'information no available' (Site from Safety).	Jennifer Molstead (b) (4)	(b) (4) 14 Sep 2020 01:37:27
Query 'PV Query: Was the subject in normal sinus rhythm at discharge? If so, was this confirmed by EKG?' answered with 'information not available' (Site from Safety).	Jennifer Molstead (b) (4)	(b) (4) 14 Sep 2020 01:36:57
Query 'PV Query: Did the patient require any treatment for hypotension or antiarrhythmics, etc. for atrial flutter? If so, please add to concomitant medication eCRF.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	(b) (4) 14 Sep 2020 01:35:21

v6.020 DTW (1102)

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: The event was reported as resolved with sequelae. Please provide the sequelae.' answered with 'subject is following up with cardiologist' (Site from Safety).	Jennifer Molstead (b) (4)	14 Sep 2020 01:35:07
Query 'PV query: The subject was prescribed levofloxacin after UTI was suspected, but the cultures were done after next visit to the ER. Did the subject take levofloxacin tablets before the cultures?' answered with 'yes' (Site from Safety).	Jennifer Molstead (b) (4)	14 Sep 2020 01:33:24
Query 'PV query: Did the subject have fever before the event and after dose 1? If yes, what severity?' answered with 'no' (Site from Safety).	Jennifer Molstead (b) (4)	14 Sep 2020 01:33:03
Query 'PV Query: Please confirm if an EKG was done on 26 Aug 2020, when the subject's heart rate was 136. If so, please provide results. If atrial flutter was confirmed on this date, please consider amending event start date.' answered with 'ECG was not done in office' (Site from Safety).	Jennifer Molstead (b) (4)	14 Sep 2020 01:32:46
User opened query 'Did the subject ever experience any arrhythmia or other cardiac event? Please provide a detailed cardiac history.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:46:58
User opened query 'PV Query: Please provide repeat vital signs at discharge.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:45:58
User opened query 'PV Query: Please provide the cardiologist assessment from the consultation.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:45:31
User opened query 'PV Query: Was the subject in normal sinus rhythm at discharge? If so, was this confirmed by EKG?' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:45:05
User opened query 'PV Query: Please provide results of any diagnostic tests performed (i.e. EKG, echocardiogram, etc.).' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:44:43
User opened query 'PV Query: Did the patient require any treatment for hypotension or antiarrhythmics, etc. for atrial flutter? If so, please add to concomitant medication eCRF.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:44:33
User opened query 'PV query: The subject was prescribed levofloxacin after UTI was suspected, but the cultures were done after next visit to the ER. Did the subject take levofloxacin tablets before the cultures?' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:44:17

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV query: Did the subject have fever before the event and after dose 1? If yes, what severity?' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:43:54
User opened query 'PV Query: The event was reported as resolved with sequelae. Please provide the sequelae.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:42:51
User opened query 'PV Query: Please confirm if an EKG was done on 26 Aug 2020, when the subject's heart rate was 136. If so, please provide results. If atrial flutter was confirmed on this date, please consider amending event start date.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 17:42:29
User entered 'Subject presented in office 26/Aug/2020 for a convalescent day 1 visit. His pulse was noted to be 139. He also stated that he thought he was having symptoms of an urinary infection. He was advised to go to the emergency room at that point. Which he declined. He was given levofloxacin 500mg po for 10 days. When he came to leave his day 3 saliva sample it was noted that the patient was not any better. Patient stated that he was unsteady on his feet and had fallen prior to coming to drop off sample. It was again recommended that the subject go to the ER. Which he did. Due to subject falling he had a CT of the head and brain, that were negative. Also a chest x-ray that was negative. Subjects blood pressure in the Er was 86/70 heart rate 134 and a resp rate of 20. Subject has various labs, of note were CRP 14, CO2 20, Bun 36, Creatinine 1.9. It was thought that he had Urosepsis and was started on Rocephin, while awaiting urine and blood culture results which were negative. Subject was admitted with a diagnosis of atrial flutter. A consult with cardiology was conducted, and patient was started on 5 mg Eliquis daily and will follow up on an out patient basis.'	Jennifer Molstead (b) (4)	02 Sep 2020 11:02:13

US3402382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 11:02:13

US3402382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 11:02:13

US3402382

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
User entered '0'	System	02 Sep 2020 11:02:13

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 16:33:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 16:33:43
Data point term sent to Coder	System	02 Nov 2020 13:09:34
User entered 'URINARY TRACT INFECTION'	Traci Hull (b) (4)	02 Nov 2020 13:09:09

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '26 Aug 2020'	Traci Hull (b) (4)	02 Nov 2020 13:09:09
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered empty.	Traci Hull (b) (4)	02 Nov 2020 13:09:09
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 13:09:09

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'No (N)'	Traci Hull (b) (4)	02 Nov 2020 13:09:09
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '6 Sep 2020'	Traci Hull (b) (4)	02 Nov 2020 13:09:09
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered empty.	Traci Hull (b) (4)	02 Nov 2020 13:09:09
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 13:09:09

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'No (N)'	Traci Hull (b) (4)	02 Nov 2020 13:09:09
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Traci Hull (b) (4)	02 Nov 2020 13:09:09
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Traci Hull (b) (4)	02 Nov 2020 13:09:09
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Traci Hull (b) (4)	02 Nov 2020 13:09:09
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered empty.	Traci Hull (b) (4)	02 Nov 2020 13:09:09
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered empty.	Traci Hull (b) (4)	02 Nov 2020 13:09:09
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered empty.	Traci Hull (b) (4)	02 Nov 2020 13:09:09
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered empty.	Traci Hull (b) (4)	02 Nov 2020 13:09:09
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Traci Hull (b) (4)	02 Nov 2020 13:09:09
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Traci Hull (b) (4)	02 Nov 2020 13:09:09
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Traci Hull (b) (4)	02 Nov 2020 13:09:09
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'Not Related (NOT RELATED)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 04:14:20
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:01:11
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 13:43:33
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 13:43:27
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 13:43:27
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:22:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'Not Applicable (NOT APPLICABLE)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'None (NONE)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Traci Hull (b) (4)	02 Nov 2020 13:09:09
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '1'	Traci Hull (b) (4)	02 Nov 2020 13:09:09
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered '0'	Traci Hull (b) (4)	02 Nov 2020 13:09:09
	(b) (4)	

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered empty.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:55:43
User entered empty.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:09:09

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	02 Nov 2020 13:09:09

US3402382

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:28:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 13:09:09

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:28:09

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User closed query 'Per SAE summary - subject received Levofloxacin for AE UTI and Eliquis for AE Atrial Flutter - medications were added to ConMeds but fields inactivated. Please provide a reason for this.	(b) (4), (b) (6)	11 Nov 2020 15:40:09
Also per source ConMeds log - Keflex 500mg PO, QD was given from 26 Aug 2020 - 06 Sep 2020 for UTI - Please add this to ConMeds log in EDC.' (Site from CRA).		
Query 'Per SAE summary - subject received Levofloxacin for AE UTI and Eliquis for AE Atrial Flutter - medications were added to ConMeds but fields inactivated. Please provide a reason for this.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:55
Also per source ConMeds log - Keflex 500mg PO, QD was given from 26 Aug 2020 - 06 Sep 2020 for UTI - Please add this to ConMeds log in EDC.' answered with 'updated' (Site from CRA).	(b) (4)	
User opened query 'Per SAE summary - subject received Levofloxacin for AE UTI and Eliquis for AE Atrial Flutter - medications were added to ConMeds but fields inactivated. Please provide a reason for this.	(b) (4), (b) (6)	10 Nov 2020 21:33:58
Also per source ConMeds log - Keflex 500mg PO, QD was given from 26 Aug 2020 - 06 Sep 2020 for UTI - Please add this to ConMeds log in EDC.' (Site from CRA).		
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:35
User closed query 'Per ETRTR: Please add medication dosed for SAE Atrial Flutter, thanks.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:28:34
Query 'Per ETRTR: Please add medication dosed for SAE Atrial Flutter, thanks.' answered with 'will update' (Site from CRA).	Jennifer Molstead (b) (4)	16 Sep 2020 14:58:38
User opened query 'Per ETRTR: Please add medication dosed for SAE Atrial Flutter, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Sep 2020 14:59:54

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:28:09

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Traci Hull (b) (4)	17 Aug 2020 20:48:54
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 12:04:11

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIMEPIRIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 20:52:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 20:52:22
	(b) (4)	
Data point term sent to Coder	System	17 Aug 2020 20:51:09
User entered 'glimepiride'	Traci Hull (b) (4)	17 Aug 2020 20:50:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:50:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'DIABETES TYPE 2'	Traci Hull (b) (4)	17 Aug 2020 20:50:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '2'	Traci Hull (b) (4)	17 Aug 2020 20:50:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4)	17 Aug 2020 20:50:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:50:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4)	17 Aug 2020 20:50:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:50:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	17 Aug 2020 20:50:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:50:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '21 Jul 2020'	Traci Hull (b) (4)	17 Aug 2020 20:50:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4)	17 Aug 2020 20:50:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4)	17 Aug 2020 20:50:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:50:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:50:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:50:13

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:50:13

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:50:13

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
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)	23 Oct 2020 14:05:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 14:05:28
Data point term sent to Coder Coding entries removed.	System Tammy Kohn (b) (4)	23 Oct 2020 14:04:49 23 Oct 2020 14:03:58
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)	17 Aug 2020 20:53:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:53:14
Data point term sent to Coder User entered 'ASPIRIN'	System Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:52:12 17 Aug 2020 20:51:14

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4)	17 Aug 2020 20:51:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User closed query 'Per CDM re-query: Previous response noted, however the Indication is still recorded as 'CARDIAC'. Please review and update the Indication to reflect the underlying medical condition.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 11:51:03
Query 'Per CDM re-query: Previous response noted, however the Indication is still recorded as 'CARDIAC'. Please review and update the Indication to reflect the underlying medical condition.' answered with 'HEART ATTACK' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Oct 2020 14:04:07
User entered 'HEART ATTACK' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Oct 2020 14:03:58
User opened query 'Per CDM re-query: Previous response noted, however the Indication is still recorded as 'CARDIAC'. Please review and update the Indication to reflect the underlying medical condition.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 12:25:41
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:42:02
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Update eCRF as appropriate.' answered with 'HEART ATTACK' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	21 Sep 2020 20:43:06
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:03:49
User entered 'CARDIAC'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:51:14

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '81'	Traci Hull (b) (4)	17 Aug 2020 20:51:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4)	17 Aug 2020 20:51:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:51:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4)	17 Aug 2020 20:51:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:51:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	17 Aug 2020 20:51:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:51:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 05:21:53
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	17 Aug 2020 21:04:43
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 20:51:14
User entered '25 Aug 2008'	Traci Hull (b) (4)	17 Aug 2020 20:51:14

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4)	17 Aug 2020 20:51:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4)	17 Aug 2020 20:51:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:51:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:51:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:51:14

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:51:14

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:51:14

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: SILDENAFIL, PRODUCTSYNONYM: VIAGRA [SILDENAFIL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 22:57:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	17 Aug 2020 22:57:16
Data point term sent to Coder	System	17 Aug 2020 20:52:12
User entered 'VIAGARA'	Traci Hull (b) (4)	17 Aug 2020 20:52:08
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:52:08
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'ERECTILE DYSFUNCTION'	Traci Hull (b) (4)	17 Aug 2020 20:52:08
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '100'	Traci Hull (b) (4)	17 Aug 2020 20:52:08
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4)	17 Aug 2020 20:52:08
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:52:08
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'as needed (PRN)'	Traci Hull (b) (4)	17 Aug 2020 20:52:08
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:52:08
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	17 Aug 2020 20:52:08
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:52:08
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 05:25:00
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	17 Aug 2020 21:04:37
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 20:52:08
User entered '25 Aug 2008'	Traci Hull (b) (4)	17 Aug 2020 20:52:08
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4)	17 Aug 2020 20:52:08
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4)	17 Aug 2020 20:52:08
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:52:08
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:52:08
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 20:52:08

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 20:52:08

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 20:52:08

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
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)	17 Aug 2020 20:54:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:54:15
Data point term sent to Coder	System	17 Aug 2020 20:53:15
User entered 'METOPROLOL ER'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:53:02

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:53:02
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'HYPERTENSION'	Traci Hull (b) (4)	17 Aug 2020 20:53:02
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '50'	Traci Hull (b) (4)	17 Aug 2020 20:53:02
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4)	17 Aug 2020 20:53:02
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:53:02
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4)	17 Aug 2020 20:53:02
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:53:02
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	17 Aug 2020 20:53:02
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:53:02
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 05:20:07
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	17 Aug 2020 21:04:29
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 20:53:02
User entered '25 Apr 2008'	Traci Hull (b) (4)	17 Aug 2020 20:53:02
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4)	17 Aug 2020 20:53:02
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4)	17 Aug 2020 20:53:02
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:53:02
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:53:02
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:53:02

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:53:02

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:53:02

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
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)	17 Aug 2020 20:55:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 20:55:16
Data point term sent to Coder	System	17 Aug 2020 20:54:16
User entered 'ATORVASTATIN'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:54:04

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:54:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'HYPERLIPIDEMIA'	Traci Hull (b) (4)	17 Aug 2020 20:54:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '40'	Traci Hull (b) (4)	17 Aug 2020 20:54:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4)	17 Aug 2020 20:54:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:54:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4)	17 Aug 2020 20:54:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:54:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	17 Aug 2020 20:54:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:54:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 05:20:33
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	17 Aug 2020 21:04:22
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 20:54:04
User entered '10 Feb 2015'	Traci Hull (b) (4)	17 Aug 2020 20:54:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4)	17 Aug 2020 20:54:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4)	17 Aug 2020 20:54:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:54:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:54:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:54:04

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:54:04

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:54:04

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 20:56:18
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 20:56:18
	(b) (4)	
Data point term sent to Coder	System	17 Aug 2020 20:55:17
User entered 'tamsulosin'	Traci Hull (b) (4)	17 Aug 2020 20:55:06
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:55:06
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'BENIGN PROSTATIC HYPERTROPHY'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:55:06

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0.4'	Traci Hull (b) (4)	17 Aug 2020 20:55:06
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4)	17 Aug 2020 20:55:06
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:55:06
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4)	17 Aug 2020 20:55:06
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:55:06
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	17 Aug 2020 20:55:06
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:55:06
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 05:20:55
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	17 Aug 2020 21:04:16
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 20:55:06
User entered '01 Sep 2017'	Traci Hull (b) (4)	17 Aug 2020 20:55:06
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4)	17 Aug 2020 20:55:06
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4)	17 Aug 2020 20:55:06
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:55:06
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:55:06
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:55:06

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:55:06

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:55:06

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: FEBUXOSTAT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 00:28:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 00:28:20
Data point term sent to Coder	System	17 Aug 2020 20:57:20
User entered 'febuxostat'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:56:26

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:56:26
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User closed query 'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:42:12
Query 'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with Med History eCRF as appropriate. ' answered with 'LEFT BIG TOE' (Site from DM).	Tammy Kohn (b) (4)	22 Sep 2020 20:28:57
User opened query 'Per DM CLR: Please update the indication to reflect the location of GOUT. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:04:19
User entered 'GOUT'	Traci Hull (b) (4)	17 Aug 2020 20:56:26

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '40'	Traci Hull (b) (4)	17 Aug 2020 20:56:26
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4)	17 Aug 2020 20:56:26
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:56:26
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4)	17 Aug 2020 20:56:26
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:56:26
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	17 Aug 2020 20:56:26
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:56:26
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 05:26:27
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	17 Aug 2020 21:04:09
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 20:56:26
User entered '25 Oct 2017'	Traci Hull (b) (4)	17 Aug 2020 20:56:26
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4)	17 Aug 2020 20:56:26
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4)	17 Aug 2020 20:56:26
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:56:26
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:56:26
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:56:26

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:56:26

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:56:26

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 12:00:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 12:00:43
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
Data point term sent to Coder DataPoint Un-verified.	System Tammy Kohn (b) (4)	11 Nov 2020 16:28:11 11 Nov 2020 16:27:58
Coding entries removed.	(b) (4) Tammy Kohn (b) (4)	11 Nov 2020 16:27:58
User entered 'VOLTAREN 1%' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	11 Nov 2020 16:27:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:53:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:53:26
Data point term sent to Coder	System	17 Aug 2020 20:57:21
User entered 'VOLTAREN'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:16

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:57:16
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'OSTEOARTHRITIS BILATERAL HIPS'	Traci Hull (b) (4)	17 Aug 2020 20:57:16
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
User closed query 'Per source dose is listed as 1%. Please enter 1 for dose, other for unit and % for other field. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 21:56:27
Query 'Per source dose is listed as 1%. Please enter 1 for dose, other for unit and % for other field. Please verify and update accordingly.' answered with 'DATA UPDATED' (Site from CRA).	Tammy Kohn (b) (4)	11 Nov 2020 16:32:43
DataPoint Un-verified.	Tammy Kohn (b) (4)	11 Nov 2020 16:32:34
User entered '1' reason for change: Data Entry Error	Tammy Kohn (b) (4)	11 Nov 2020 16:32:34
User opened query 'Per source dose is listed as 1%. Please enter 1 for dose, other for unit and % for other field. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:35:18
User closed query 'Per source dose is listed as 1%. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:35:18
Query 'Per source dose is listed as 1%. Please verify and update accordingly.' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	10 Nov 2020 21:38:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User opened query 'Per source dose is listed as 1%. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:24:09
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 18:43:21

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

[Dose per administration](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Sep 2020 11:34:03
User entered '100' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Sep 2020 11:33:49
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. (Site from DM).	(b) (4), (b) (6) (b) (4)	21 Sep 2020 14:04:41
User entered '1'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:16

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint Un-verified.	Tammy Kohn (b) (4)	11 Nov 2020 16:32:34
	(b) (4)	
User entered 'Other (OTHER)' reason for change:	Tammy Kohn (b) (4)	11 Nov 2020 16:32:34
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'g (g)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	23 Sep 2020 11:33:49
	(b) (4)	
User entered 'Other (OTHER)'	Traci Hull (b) (4)	17 Aug 2020 20:57:16
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint Un-verified.	Tammy Kohn (b) (4)	11 Nov 2020 16:32:34
	(b) (4)	
User entered '%' reason for change: Data Entry Error	Tammy Kohn (b) (4)	11 Nov 2020 16:32:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	23 Sep 2020 11:33:49
	(b) (4)	
User entered '%'	Traci Hull (b) (4)	17 Aug 2020 20:57:16
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4)	17 Aug 2020 20:57:16
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:57:16
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Topical (TOPICAL)'	Traci Hull (b) (4)	17 Aug 2020 20:57:16
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:57:16
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 05:25:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Traci Hull (b) (4)	17 Aug 2020 21:04:02
answered with 'ONGOING' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 20:57:16
User entered '25 Apr 2018'	Traci Hull (b) (4)	17 Aug 2020 20:57:16
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4)	17 Aug 2020 20:57:16
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4)	17 Aug 2020 20:57:16
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:57:16
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:57:16
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:57:16

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:57:16

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:57:16

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: OZEMPIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 13:06:32
	(b) (4)	
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 13:06:32
	(b) (4)	
Data point term sent to Coder	System	19 Oct 2020 13:05:53
Coding entries removed.	Tammy Kohn (b) (4)	19 Oct 2020 13:05:18
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: OZEMPIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 11:37:52
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 11:37:52
	(b) (4)	
Data point term sent to Coder	System	23 Sep 2020 11:37:11
Coding entries removed.	Tammy Kohn (b) (4)	23 Sep 2020 11:37:02
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: OZEMPIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 20:59:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 20:59:21
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	17 Aug 2020 20:58:25
User entered 'OZEMPIC'	Traci Hull (b) (4)	17 Aug 2020 20:57:53
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:57:53
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'DIABETES TYPE 2'	Traci Hull (b) (4)	17 Aug 2020 20:57:53
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '1'	Traci Hull (b) (4)	17 Aug 2020 20:57:53
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4)	17 Aug 2020 20:57:53
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:57:53
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 06:32:30
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:11:19
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:11:11
User entered 'every week (QS)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:11:11
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 11:40:44
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 20:57:53

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:57:53
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Per source route of administration is PO. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:36:21
Query 'Per source route of administration is PO. Please verify and update accordingly. ' answered with 'source updated' (Site from CRA).	Jennifer Molstead (b) (4)	10 Nov 2020 21:39:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User opened query 'Per source route of administration is PO. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:25:11
User closed query 'Per DM CLR-RQ: Updated route to INTRAMUSCULAR. However, this route is also not an expected/usual route for this CM. Please review and verify source documents and update if applicable. Otherwise, provide confirmation/clarification.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 11:50:50
Query 'Per DM CLR-RQ: Updated route to INTRAMUSCULAR. However, this route is also not an expected/usual route for this CM. Please review and verify source documents and update if applicable. Otherwise, provide confirmation/clarification.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	19 Oct 2020 13:05:24
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	(b) (4)	19 Oct 2020 13:05:18
User opened query 'Per DM CLR-RQ: Updated route to INTRAMUSCULAR. However, this route is also not an expected/usual route for this CM. Please review and verify source documents and update if applicable. Otherwise, provide confirmation/clarification.' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 15:21:31
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 18:43:33
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	23 Sep 2020 11:37:12

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Tammy Kohn (b) (4)	23 Sep 2020 11:37:02
reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please review the	(b) (4), (b) (6)	21 Sep 2020 14:05:22
Route as this medication is not typically administered		
as indicated. Please update route as appropriate.		
' (Site from DM).		
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	17 Aug 2020 20:57:53
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:57:53
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 05:25:28
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	17 Aug 2020 21:03:54
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 20:57:53
User entered '05 Nov 2018'	Traci Hull (b) (4)	17 Aug 2020 20:57:53
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4)	17 Aug 2020 20:57:53
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4)	17 Aug 2020 20:57:53
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:57:53
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:57:53
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:57:53

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:57:53

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	16 Nov 2020 19:11:11
User entered '804 (804)'	System	17 Aug 2020 20:57:53

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 20:59:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 20:59:22
	(b) (4)	
Data point term sent to Coder	System	17 Aug 2020 20:58:25
User entered 'DULOXETINE'	Traci Hull (b) (4)	17 Aug 2020 20:58:24
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:58:24
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'ANXIETY'	Traci Hull (b) (4)	17 Aug 2020 20:58:24
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '60'	Traci Hull (b) (4)	17 Aug 2020 20:58:24
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4)	17 Aug 2020 20:58:24
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:58:24
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4)	17 Aug 2020 20:58:24
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:58:24
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	17 Aug 2020 20:58:24
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:58:24
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 05:26:08
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	17 Aug 2020 21:03:46
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 20:58:24
User entered '05 Nov 2018'	Traci Hull (b) (4)	17 Aug 2020 20:58:24
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4)	17 Aug 2020 20:58:24
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4)	17 Aug 2020 20:58:24
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:58:24
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:58:24
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:58:24

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:58:24

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:58:24

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 21:00:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 21:00:22
	(b) (4)	
Data point term sent to Coder	System	17 Aug 2020 20:59:25
User entered 'JARDIANCE'	Traci Hull (b) (4)	17 Aug 2020 20:59:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:59:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'DIABETES TYPE 2'	Traci Hull (b) (4)	17 Aug 2020 20:59:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '25'	Traci Hull (b) (4)	17 Aug 2020 20:59:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4)	17 Aug 2020 20:59:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:59:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4)	17 Aug 2020 20:59:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:59:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	17 Aug 2020 20:59:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:59:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 05:26:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Traci Hull (b) (4)	17 Aug 2020 21:03:39
answered with 'ONGOING' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 20:59:14
User entered '18 Apr 2017'	Traci Hull (b) (4)	17 Aug 2020 20:59:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4)	17 Aug 2020 20:59:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4)	17 Aug 2020 20:59:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 20:59:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 20:59:14
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:59:14

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 20:59:14

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 20:59:14

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 21:01:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 21:01:27
Data point term sent to Coder	System	17 Aug 2020 21:00:28
User entered 'hydrocodone'	Traci Hull (b) (4)	17 Aug 2020 21:00:04

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 21:00:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User closed query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:42:30
Query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS. Please reconcile with Med History eCRF as appropriate. ' answered with 'OSTEOARTHRITIS IS THROUGH OUT THE BODY' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	23 Sep 2020 11:38:06
User opened query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:05:51
User entered 'OSTEOARTHRITIS'	Traci Hull (b) (4) (b) (4)	17 Aug 2020 21:00:04

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '5'	Traci Hull (b) (4)	17 Aug 2020 21:00:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4)	17 Aug 2020 21:00:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 21:00:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4)	17 Aug 2020 21:00:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 21:00:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	17 Aug 2020 21:00:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 21:00:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 05:21:30
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	17 Aug 2020 21:03:33
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 21:00:04
User entered '31 Oct 2019'	Traci Hull (b) (4)	17 Aug 2020 21:00:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4)	17 Aug 2020 21:00:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4)	17 Aug 2020 21:00:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 21:00:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 21:00:04
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 21:00:04

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 21:00:04

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 21:00:04

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 21:02:16
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 21:02:16
	(b) (4)	
Data point term sent to Coder	System	17 Aug 2020 21:01:30
User entered 'COLACE'	Traci Hull (b) (4)	17 Aug 2020 21:00:41
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 21:00:41
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'CONSTIPATION'	Traci Hull (b) (4)	17 Aug 2020 21:00:41
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '100'	Traci Hull (b) (4)	17 Aug 2020 21:00:41
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4)	17 Aug 2020 21:00:41
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 21:00:41
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4)	17 Aug 2020 21:00:41
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 21:00:41
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	17 Aug 2020 21:00:41
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 21:00:41
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 05:27:01
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	17 Aug 2020 21:03:26
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 21:00:41
User entered '04 Nov 2019'	Traci Hull (b) (4)	17 Aug 2020 21:00:41
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4)	17 Aug 2020 21:00:41
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4)	17 Aug 2020 21:00:41
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 21:00:41
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 21:00:41
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 21:00:41

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 21:00:41

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 21:00:41

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 07:12:26
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 07:12:26
	(b) (4)	
Data point term sent to Coder	System	17 Aug 2020 21:03:33
User entered 'LANTUS SOLOSTAR'	Traci Hull (b) (4)	17 Aug 2020 21:03:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 21:03:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'TYPE 2 DIABETES'	Traci Hull (b) (4)	17 Aug 2020 21:03:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '100'	Traci Hull (b) (4)	17 Aug 2020 21:03:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Other (OTHER)'	Traci Hull (b) (4)	17 Aug 2020 21:03:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'UNITS'	Traci Hull (b) (4)	17 Aug 2020 21:03:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4)	17 Aug 2020 21:03:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 21:03:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Subcutaneous (SUBCUTANEOUS)'	Traci Hull (b) (4)	17 Aug 2020 21:03:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 21:03:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 05:27:15
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Traci Hull (b) (4)	17 Aug 2020 21:03:19
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 21:03:13
User entered '04 Nov 2019'	Traci Hull (b) (4)	17 Aug 2020 21:03:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4)	17 Aug 2020 21:03:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Yes (Y)'	Traci Hull (b) (4)	17 Aug 2020 21:03:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	17 Aug 2020 21:03:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 21:03:13
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 21:03:13

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Aug 2020 21:03:13

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Aug 2020 21:03:13

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

[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: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 19:56:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 19:56:51
Data point term sent to Coder	System	16 Nov 2020 19:56:23
Coding entries removed.	Tammy Kohn (b) (4)	16 Nov 2020 19:55:39
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 21:41:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 21:41:43
Data point term sent to Coder	System	10 Nov 2020 21:41:16
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:24
Data point term sent to Coder	System	02 Nov 2020 13:06:30
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:05:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 17:59:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 17:59:32

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	01 Oct 2020 17:57:32
User entered 'ELIQUIS'	Tammy Kohn (b) (4)	01 Oct 2020 17:56:35
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Traci Hull (b) (4)	02 Nov 2020 13:05:57
	(b) (4)	
User entered 'No (N)'	Tammy Kohn (b) (4)	01 Oct 2020 17:56:35
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 06:33:21
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match. ' answered with 'DATA UPDATED ALREADY AN AE' (Site from DM). DataPoint Un-verified.	Tammy Kohn (b) (4)	16 Nov 2020 19:55:48
User entered 'ATRIAL FIBRILLATION' reason for change: Data Entry Error	Tammy Kohn (b) (4)	16 Nov 2020 19:55:39
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the DRUG ACTION/CLASS. Please reconcile with AE or Med History eCRF so there is an appropriate match. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 11:39:52
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	11 Nov 2020 21:56:30
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	10 Nov 2020 21:40:24
User entered 'anticoagulant medication'	Tammy Kohn (b) (4)	02 Nov 2020 13:05:57
	(b) (4)	01 Oct 2020 17:56:35

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:05:57
User entered '5'	Tammy Kohn (b) (4)	01 Oct 2020 17:56:35
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:05:57
User entered 'mg (mg)'	Tammy Kohn (b) (4)	01 Oct 2020 17:56:35
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:05:57
User entered empty.	Tammy Kohn (b) (4)	01 Oct 2020 17:56:35
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:05:57
User entered 'once daily (QD)'	Tammy Kohn (b) (4)	01 Oct 2020 17:56:35

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:05:57
User entered empty.	Tammy Kohn (b) (4)	01 Oct 2020 17:56:35

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:05:57
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4)	01 Oct 2020 17:56:35

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:05:57
User entered empty.	Tammy Kohn (b) (4)	01 Oct 2020 17:56:35

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:05:57
User entered '28 Aug 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4)	01 Oct 2020 17:58:26
User entered '16 Sep 2020'	Tammy Kohn (b) (4)	01 Oct 2020 17:56:35

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:05:57
	(b) (4)	
User entered '0'	Tammy Kohn (b) (4)	01 Oct 2020 17:56:35
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:05:57
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	01 Oct 2020 17:56:35
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:05:57
User entered empty.	Tammy Kohn (b) (4)	01 Oct 2020 17:56:35
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:03:57
DataPoint Un-verified.	Tammy Kohn (b) (4)	16 Nov 2020 19:55:53
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	16 Nov 2020 19:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:24
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:05:57
	(b) (4)	
User entered 'No (N)'	Tammy Kohn (b) (4)	01 Oct 2020 17:56:35
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:05:57
User entered '1'	System	01 Oct 2020 17:56:35

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:05:57
User entered '1'	System	01 Oct 2020 17:56:35

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:24
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:05:57
User entered '804 (804)'	System	01 Oct 2020 17:56:35

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Nov 2020 20:49:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Nov 2020 20:49:54
Data point term sent to Coder Coding entries removed.	System	16 Nov 2020 19:55:22
	Tammy Kohn (b) (4)	16 Nov 2020 19:54:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 21:56:30
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 21:41:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 21:41:41
Data point term sent to Coder	System	10 Nov 2020 21:41:16
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:29
Data point term sent to Coder	System	02 Nov 2020 13:06:30
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:06:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Oct 2020 22:52:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Oct 2020 22:52:51

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	01 Oct 2020 18:01:41
User entered 'LEVOFLOXACIN'	Tammy Kohn (b) (4)	01 Oct 2020 18:00:59
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:06:03
User entered 'No (N)'	Tammy Kohn (b) (4)	01 Oct 2020 18:00:59

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 06:33:51
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:04:05
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'DATA UPDATED THIS IS ALREADY AN AE DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:54:46
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:54:30
User entered 'URINARY TRACT INFECTION BACTERIA' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Nov 2020 19:54:30
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 11:40:13
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4) (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4) (b) (4)	02 Nov 2020 13:06:03
User entered 'bacteria infection'	Tammy Kohn (b) (4) (b) (4)	01 Oct 2020 18:00:59

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:06:03
User entered '500'	Tammy Kohn (b) (4)	01 Oct 2020 18:00:59
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:06:03
User entered 'mg (mg)'	Tammy Kohn (b) (4)	01 Oct 2020 18:00:59
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:06:03
User entered empty.	Tammy Kohn (b) (4)	01 Oct 2020 18:00:59

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:06:03
User entered 'once daily (QD)'	Tammy Kohn (b) (4)	01 Oct 2020 18:00:59

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:06:03
User entered empty.	Tammy Kohn (b) (4)	01 Oct 2020 18:00:59

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:06:03
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4)	01 Oct 2020 18:00:59

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:29
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:06:03
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	01 Oct 2020 18:00:59
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:06:03
User entered '28 Aug 2020'	Tammy Kohn (b) (4)	01 Oct 2020 18:00:59

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:06:03
User entered '0'	Tammy Kohn (b) (4)	01 Oct 2020 18:00:59
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:06:03
User entered 'No (N)'	Tammy Kohn (b) (4)	01 Oct 2020 18:00:59

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
User entered '08 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 14:00:23
	(b) (4)	
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:29
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:06:03
	(b) (4)	
User entered '8 Sep 2020'	Tammy Kohn (b) (4)	01 Oct 2020 18:00:59
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:04:09
DataPoint Un-verified.	Tammy Kohn (b) (4)	16 Nov 2020 19:54:51
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	16 Nov 2020 19:54:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:56:30
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:29
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:06:03
	(b) (4)	
User entered 'No (N)'	Tammy Kohn (b) (4)	01 Oct 2020 18:00:59
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:06:03
User entered '1'	System	01 Oct 2020 18:00:59

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:06:03
User entered '1'	System	01 Oct 2020 18:00:59

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Jennifer Molstead (b) (4)	10 Nov 2020 21:40:29
DataPoint inactivated with code reason code Data not required.	Traci Hull (b) (4)	02 Nov 2020 13:06:03
User entered '804 (804)'	System	01 Oct 2020 18:00:59

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: KEFLEX [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 16:11:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	03 Nov 2020 16:11:36
Data point term sent to Coder User entered 'KEFLEX'	System Traci Hull (b) (4)	02 Nov 2020 13:07:33 02 Nov 2020 13:07:21

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	02 Nov 2020 13:07:21
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'URINARY TRACT INFECTION'	Traci Hull (b) (4)	02 Nov 2020 13:07:21
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '500'	Traci Hull (b) (4)	02 Nov 2020 13:07:21
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'mg (mg)'	Traci Hull (b) (4)	02 Nov 2020 13:07:21
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	02 Nov 2020 13:07:21
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'once daily (QD)'	Traci Hull (b) (4)	02 Nov 2020 13:07:21
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	02 Nov 2020 13:07:21
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	02 Nov 2020 13:07:21
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered empty.	Traci Hull (b) (4)	02 Nov 2020 13:07:21
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '26 Aug 2020'	Traci Hull (b) (4)	02 Nov 2020 13:07:21
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '0'	Traci Hull (b) (4)	02 Nov 2020 13:07:21
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	02 Nov 2020 13:07:21
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:41
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 14:00:36
	(b) (4)	
User entered '06 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 14:00:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered '6 Sep 2020'	Traci Hull (b) (4)	02 Nov 2020 13:07:21
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:05
User entered 'No (N)'	Traci Hull (b) (4)	02 Nov 2020 13:07:21
	(b) (4)	

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 13:07:21

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 13:07:21

US3402382

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:28:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 13:07:21

US3402382

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:28:09

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:04:34
User entered 'No (N)'	Traci Hull (b) (4)	17 Aug 2020 12:03:47
	(b) (4)	

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'USA-US059-2020-MRNA-1273-P301000002'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:33:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered 'US' (non-conformant).	System	02 Sep 2020 13:12:53

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Nov 2020 16:14:45
User entered '5'	System	02 Nov 2020 14:29:35
User entered '4'	System	30 Oct 2020 14:04:04
User entered '3'	System	30 Sep 2020 17:21:46
User entered '2'	System	14 Sep 2020 20:29:42
User entered '1'	System	02 Sep 2020 13:12:53

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'USA-US059-2020-MRNA-1273-P301000002'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:33:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered 'US' (non-conformant).	System	02 Sep 2020 13:12:53

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Nov 2020 16:14:45
User entered '5'	System	02 Nov 2020 14:29:35
User entered '4'	System	30 Oct 2020 14:04:04
User entered '3'	System	30 Sep 2020 17:21:46
User entered '2'	System	14 Sep 2020 20:29:42
User entered '1'	System	02 Sep 2020 13:12:53

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:28:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
User entered '02/Sep/2020 09:12'	System	02 Sep 2020 13:12:53

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:28:09

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)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered '1'	(b) (4), (b) (6)	02 Sep 2020 13:12:53

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'USA-US059-2020-MRNA-1273-P301000002'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:33:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered 'US' (non-conformant).	System	02 Sep 2020 13:12:53

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Nov 2020 16:14:45
User entered '5'	System	02 Nov 2020 14:29:35
User entered '4'	System	30 Oct 2020 14:04:04
User entered '3'	System	30 Sep 2020 17:21:46
User entered '2'	System	14 Sep 2020 20:29:42
User entered '1'	System	02 Sep 2020 13:12:53

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:28:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
User entered '14/Sep/2020 16:29'	System	14 Sep 2020 20:29:42

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:28:09

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)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
User entered '1'	(b) (4), (b) (6)	14 Sep 2020 20:29:42

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'USA-US059-2020-MRNA-1273-P301000002'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:33:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered 'US' (non-conformant).	System	02 Sep 2020 13:12:53

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Nov 2020 16:14:45
User entered '5'	System	02 Nov 2020 14:29:35
User entered '4'	System	30 Oct 2020 14:04:04
User entered '3'	System	30 Sep 2020 17:21:46
User entered '2'	System	14 Sep 2020 20:29:42
User entered '1'	System	02 Sep 2020 13:12:53

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:28:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
User entered '30/Sep/2020 17:21'	System	30 Sep 2020 17:21:46

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:28:09

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)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 14:03:54
User entered '1'	(b) (4), (b) (6)	30 Sep 2020 17:21:46

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'USA-US059-2020-MRNA-1273-P301000002'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:33:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered 'US' (non-conformant).	System	02 Sep 2020 13:12:53

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Nov 2020 16:14:45
User entered '5'	System	02 Nov 2020 14:29:35
User entered '4'	System	30 Oct 2020 14:04:04
User entered '3'	System	30 Sep 2020 17:21:46
User entered '2'	System	14 Sep 2020 20:29:42
User entered '1'	System	02 Sep 2020 13:12:53

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:28:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
User entered '30/Oct/2020 14:04'	System	30 Oct 2020 14:04:04

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:28:09

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)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:29:23
User entered '1'	(b) (4), (b) (6)	30 Oct 2020 14:04:04

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'USA-US059-2020-MRNA-1273-P301000002'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:33:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered 'US' (non-conformant).	System	02 Sep 2020 13:12:53

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Nov 2020 16:14:45
User entered '5'	System	02 Nov 2020 14:29:35
User entered '4'	System	30 Oct 2020 14:04:04
User entered '3'	System	30 Sep 2020 17:21:46
User entered '2'	System	14 Sep 2020 20:29:42
User entered '1'	System	02 Sep 2020 13:12:53

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:28:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
User entered '02/Nov/2020 14:29'	System	02 Nov 2020 14:29:35

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:28:09

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)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 14:31:22
User entered '1'	(b) (4), (b) (6)	02 Nov 2020 14:29:35

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'USA-US059-2020-MRNA-1273-P301000002'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'Yes (Y)'	System	02 Sep 2020 13:11:09

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

US3402382

Folder: SAE USA-US059-2020-MRNA-1273-P301000002

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered 'No (N)'	System	02 Sep 2020 13:11:09

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

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Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

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Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

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Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

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Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

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Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:21:31
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:53:44
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:53:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 13:12:47
User entered (b) (6)	System	02 Sep 2020 13:11:09

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Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:40
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 07:33:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 20:29:32
User entered 'US' (non-conformant).	System	02 Sep 2020 13:12:53

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Form: Safety Report Form

Generated On: 26 Nov 2020 09:28:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	09 Nov 2020 16:14:45
User entered '5'	System	02 Nov 2020 14:29:35
User entered '4'	System	30 Oct 2020 14:04:04
User entered '3'	System	30 Sep 2020 17:21:46
User entered '2'	System	14 Sep 2020 20:29:42
User entered '1'	System	02 Sep 2020 13:12:53

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Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:28:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 21:02:07
User entered '09/Nov/2020 11:14'	System	09 Nov 2020 16:14:45

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Folder: SAE USA-US059-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

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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)	20 Nov 2020 21:02:08
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 16:14:45