

US3402042 (Prod: Meridian Clinical Research, LLC)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:23:19

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US3402042

Form: Participant Creation

Generated On: 26 Nov 2020 09:23:19

[Participant ID](#)

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

US3402042

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 JUL 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 09:23:19

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	72
Age Units	YEARS
Age (Derived)	72
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 09:23:19

Date of Informed Consent (<i>dd MMM yyyy</i>)	28 JUL 2020
Month and Year of Informed Consent (derived)	JUL 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 09:23:19

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:23:19

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:19

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 (3)

Generated On: 26 Nov 2020 09:23:19

Condition	BENIGN PROSTATIC HYPERTROPHY
Start date (dd MMM yyyy)	UN UNK 1992
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 1992
Start Year (derived)	1992
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:19

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

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:19

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:19

Condition	UTICARIA
Start date (dd MMM yyyy)	UN UNK 1967
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 1967
Start Year (derived)	1967
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:19

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

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:19

Condition	HIATAL HERNIA
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:19

Condition	DEPRESSION
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 (11)

Generated On: 26 Nov 2020 09:23:19

Condition	IRRITABLE BOWEL SYNDROME
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 (12)

Generated On: 26 Nov 2020 09:23:19

Condition	EMPHYSEMA
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 (13)

Generated On: 26 Nov 2020 09:23:19

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	28 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	09:30 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 09:30
Height (<i>xxx.x</i>)	165 cm
Weight (<i>xxx.x</i>)	60.8 kg
BMI (<i>xxx.x</i>)	22.33242 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	66 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>)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JUL 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 09:23:19

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☐
	No ☒
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐
	No ☒
Retail or Restaurant Operations , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐
	No ☒
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐
	No ☒
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐
	No ☒
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐
	No ☒
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐
	No ☒
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐
	No ☒
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐
	No ☒
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐
	No ☒
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐
	No ☒
Other	Yes ☐
	No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

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Folder: Screening

Form: Risk of Exposure

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 JUL 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 09:23:19

What was the date of randomization? (dd MMM yyyy) 28 JUL 2020

What was the participant's randomization number? 184073

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 ☐

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:19

Height	165 cm
Weight	60.8 kg

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

Height	165 cm
Weight	60.8 kg
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	28 JUL 2020
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 09:30
Temperature (xxx.x)	36.7 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 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 09:23:19

Height	165 cm
Weight	60.8 kg
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	28 JUL 2020
Time of assessment (00:00-23:59)	11:28 (24 HR)
Vital Signs Date and Time (derived)	28 JUL 2020 11:28
Temperature (xxx.x)	97.1 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JUL 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: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

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) 28 JUL 2020

What was the treatment time? (00:00-23:59) 10:56 (24 HR)

Treatment Date and Time (derived) 28 JUL 2020 10:56

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 09:23:19

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

28 JUL 2020

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

10:32 (24 HR)

Collection date and time (derived)

28 JUL 2020 10:32

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:19

Collection date (<i>dd MMM yyyy</i>)			28 JUL 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:22	28 JUL 2020 10:22
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

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 09:23:19

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

97.1 °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

28 JUL 2020 11:36

PC Open Date & Time

28 JUL 2020 11:16

PC Close Date & Time

28 JUL 2020 13:46

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

28 JUL 2020 14:54

PC Open Date & Time

28 JUL 2020 14:41

PC Close Date & Time

29 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:19

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

98.3 °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

29 JUL 2020 13:13

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

30 JUL 2020 12:29

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

31 JUL 2020 12:14

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

01 AUG 2020 12:08

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

02 AUG 2020 20:50

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

03 AUG 2020 12:07

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

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

28 JUL 2020 11:36

PC Open Date & Time

28 JUL 2020 11:16

PC Close Date & Time

28 JUL 2020 13:46

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

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

20

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

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

28 JUL 2020 15:01

PC Open Date & Time

28 JUL 2020 14:41

PC Close Date & Time

29 JUL 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

500

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

29 JUL 2020 13:14

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:19

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

200

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

30 JUL 2020 12:30

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:19

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

31 JUL 2020 12:14

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 12:09

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:19

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

02 AUG 2020 20:51

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:19

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

03 AUG 2020 12:08

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

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

No ☒

Yes ☐

PC Time stamp	28 JUL 2020 11:37
PC Open Date & Time	28 JUL 2020 11:16
PC Close Date & Time	28 JUL 2020 13:46

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

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

No ☒

Yes ☐

PC Time stamp	28 JUL 2020 15:02
PC Open Date & Time	28 JUL 2020 14:41
PC Close Date & Time	29 JUL 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

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 ☒

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

Yes ☐	
PC Time stamp	29 JUL 2020 13:15
PC Open Date & Time	29 JUL 2020 12:00
PC Close Date & Time	30 JUL 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

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 ☒

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

Yes ☐	
PC Time stamp	30 JUL 2020 12:31
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

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 ☒

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

Yes ☐	
PC Time stamp	31 JUL 2020 12:15
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

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 ☒

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

Yes ☐	
PC Time stamp	01 AUG 2020 12:10
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

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 ☒

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

Yes ☐	
PC Time stamp	02 AUG 2020 20:51
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

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 ☒

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

Yes ☐	
PC Time stamp	03 AUG 2020 12:08
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3402042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402042

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402042

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402042

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	25 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 09:10
Temperature (xxx.x)	36.6 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	10:44 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 10:44
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3402042

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 AUG 2020

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

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

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)	25 AUG 2020
What was the treatment time? (00:00-23:59)	10:14 (24 HR)
Treatment Date and Time (derived)	25 AUG 2020 10:14
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

US3402042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:19

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	25 AUG 2020
Collection time (<i>00:00-23:59</i>)	09:47 (24 HR)
Collection date and time (derived)	25 AUG 2020 09:47

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:19

Collection date (<i>dd MMM yyyy</i>)			25 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	09:50	25 AUG 2020 09:50
Nasopharyngeal Swab 2	No		

US3402042

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 10:47

PC Open Date & Time

25 AUG 2020 10:34

PC Close Date & Time

25 AUG 2020 13:04

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

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 99.5 °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	25 AUG 2020 16:51
PC Open Date & Time	25 AUG 2020 13:59
PC Close Date & Time	26 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:19

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

95.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 12:11

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 12:25

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 15:19

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 12:06

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 15:32

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 12:03

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

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

25 AUG 2020 10:47

PC Open Date & Time

25 AUG 2020 10:34

PC Close Date & Time

25 AUG 2020 13:04

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

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

25 AUG 2020 16:52

PC Open Date & Time

25 AUG 2020 13:59

PC Close Date & Time

26 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 12:12

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:19

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

27 AUG 2020 12:26

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:19

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

28 AUG 2020 15:19

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 12:06

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:19

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

30 AUG 2020 15:33

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:19

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

31 AUG 2020 12:03

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 10:48
PC Open Date & Time	25 AUG 2020 10:34
PC Close Date & Time	25 AUG 2020 13:04

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 16:53
PC Open Date & Time	25 AUG 2020 13:59
PC Close Date & Time	26 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

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 ☒

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

Yes ☐	
PC Time stamp	26 AUG 2020 12:13
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

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 ☒

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

Yes ☐	
PC Time stamp	27 AUG 2020 12:27
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

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 ☒

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

Yes ☐	
PC Time stamp	28 AUG 2020 15:20
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

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 ☒

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

Yes ☐	
PC Time stamp	29 AUG 2020 12:07
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

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 ☒

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

Yes ☐	
PC Time stamp	30 AUG 2020 15:33
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

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 ☒

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

Yes ☐	
PC Time stamp	31 AUG 2020 12:04
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3402042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402042

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402042

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402042

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	24 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:05 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 09:05
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402042

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:19

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.

US3402042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:19

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	24 SEP 2020
Collection time (<i>00:00-23:59</i>)	09:12 (24 HR)
Collection date and time (derived)	24 SEP 2020 09:12

US3402042

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

27 SEP 2020 10:49:50

Patient Cloud Open Date & Time

27 SEP 2020 00:01

Patient Cloud Close Date & Time

01 OCT 2020 23:59

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire 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	04 OCT 2020 11:27:56
Patient Cloud Open Date & Time	04 OCT 2020 00:01
Patient Cloud Close Date & Time	08 OCT 2020 23:59

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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	12 OCT 2020 16:39:12
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-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 ☐
Date and time of submission	25 OCT 2020 22:23:08
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-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	01 NOV 2020 19:05:22
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 22:07:41

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

DAY 113

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 22:38:51

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2020 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 10:08:55
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

Date and time of submission	
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

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16 AUG 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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30 AUG 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

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27 SEP 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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10 JAN 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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17 JAN 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

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20 JAN 2022 00:01

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24 JAN 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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31 JAN 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

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07 FEB 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

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14 FEB 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

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21 FEB 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

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28 FEB 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

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21 MAR 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

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28 MAR 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

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04 APR 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3402042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402042

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402042

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

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

US3402042

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:19

Date of Contact	12 OCT 2020
Time of Contact	14:00
Date and Time of Contact (derived)	12 OCT 2020 14:00
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 ☐

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

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	☐

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	01 OCT 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	96.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	345 of 2204	

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

	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	☐

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

	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	☐

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

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	☐

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	13 OCT 2020	
Assessment Not Done	False	
O2 Saturation	90 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	349 of 2204	

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

	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	☐

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

	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	☐

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

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	☐

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 OCT 2020	
Assessment Not Done	False	
O2 Saturation	90 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	353 of 2204	

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

	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	☐

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

	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	☐

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:19

Date of Visit	12 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☐ No ☒
Date of Test	12 OCT 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	0

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:23:19

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:23:19

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

US3402042

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

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	SICKD1

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

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>)	14:19 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 14:19
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	96.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	58 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402042

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 OCT 2020

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

US3402042

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:23:19

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

12 OCT 2020

US3402042

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

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 _____

US3402042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

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)	

US3402042

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:19

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.

US3402042

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:23:19

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3402042

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:23:19

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

AEID	USA-US059-2020-MRNA-1273-P30 1000006
Adverse event	WORSENING OF EMPHYSEMA
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)	01 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	17 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	17 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	368 of 2204

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

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	

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

SUBJECT BEGAN WITH
CONGESTION 01OCT2020 WENT
TO HIS PULMONOLOGIST AND
WAS STARTED ON
PREDNISONE AND CEFDIR.
SUBJECT CAME FOR ILLNESS
VISIT 12OCT2020. AFTER
HAVING PHYSICAL EXAM IT
WAS DETERMINED BY SUB
INVESTIGATOR THAT SUBJECT
SHOULD GO THE THE
EMERGENCY ROOM FOR
FURTHER EVALUATION.
SUBJECT WAS LATER
ADMITTED TO HOSPITAL FOR
FURTHER TREATMENT. SUBJCT
HAD CHEST XRAY WHICH
SHOWED CHANGES IN BTH
LUNGS PARTICULARLY WITH
IN THE UPPER LOBES WITH
LINEAR SCARRING WITH IN
THE MID AND LOWER LUNG
ZONES AS NOTED ON PREIOUS
STUDIES. SUBJECT IS ON 3L OF
OXYGEN BY NASAL CANNULA.
SUBJECT WILL CONTINUE ON
CEFTRIAXONE, AND
AZITHROMYCIN,. WILL BE
STARTED ON
METHYLPREDNISOLONE.

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

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:23:19

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

Yes ☒

No ☐

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

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

Name of Medication	ELIQUIS
Prophylaxis	Yes ☐ No ☒
Indication	DEEP VEIN THROMBOSIS/ PULMINARY EMBOLISM
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 ☐

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

Name of Medication	TOMSULOSIN
Prophylaxis	Yes ☐ No ☒
Indication	BENIGN PROSTATIC HYPERTROPHY
Dose per administration	.04
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 ☐

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1992
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	☒

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

Name of Medication	FLUOXETINE
Prophylaxis	Yes ☐ No ☒
Indication	DEPRESSION
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 ☐

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2012
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	☒

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

Name of Medication	BISOPROLOL
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
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 ☐

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	17 OCT 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

Name of Medication	HYDROCHLORATHIAZIDE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	6.25
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 ☐

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

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

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes ☐ No ☒
Indication	GASTROESOPHAGEAL REFLUX DISEASE
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 ☐

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
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	☒

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

Name of Medication	ROFLUMILAST
Prophylaxis	Yes ☐ No ☒
Indication	EMPHYSEMA
Dose per administration	250
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 ☐

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2016
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 ☒

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

Name of Medication	BEVESPI AEROSPHERE
Prophylaxis	Yes ☐ No ☒
Indication	EMPHYSEMA
Dose per administration	9/4.8
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 ☐

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

Name of Medication	DOXYCYCLINE
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING OF EMPHYSEMA
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 ☐

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

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)	1 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒
If not Ongoing, End date (dd MMM yyyy)	12 OCT 2020
Was this medication taken for solicited event?	Yes ☐ No ☒
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☒

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

Name of Medication	PREDNISONE
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING OF EMPHYSEMA
Dose per administration	30
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

	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 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		4 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

Name of Medication	PREDNISONE
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING OF EMPHYSEMA
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 ☐

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

	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)		5 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		6 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

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

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

	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)		7 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		8 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

Name of Medication	PREDNISONE
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING OF EMPHYSEMA
Dose per administration	15
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 ☐

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		9 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		10 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

Name of Medication	APIXABAN
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING EMPHYSEMA
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 ☐

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

	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)		12 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

Name of Medication	CEFTRIAXONE
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING EMPHYSEMA
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 ☐

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

	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 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		12 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

Name of Medication	METHYLPREDNISOLONE
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING EMPHYSEMA
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 ☐

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

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)	12 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

Name of Medication	CEFDINIR
Prophylaxis	Yes ☐ No ☒
Indication	PNEUMONIA
Dose per administration	300
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 ☐

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

	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)		17 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

Name of Medication	OXYGEN
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING EMPHYSEMA
Dose per administration	3
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	LITERS
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	CONTINUOUS
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

	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)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		17 OCT 2020
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

Name of Medication	AZITHROMYCIN
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING EMPHYSEMA
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 ☐

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

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)	12 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ☒
If not Ongoing, End date (dd MMM yyyy)	17 OCT 2020
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3402042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:23:19

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3402042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:23:19

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
12 OCT 2020	CHEST XRAY	Adverse Event	

US3402042

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:23:19

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

US3402042

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:23:19

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 ☐

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

SAEID	USA-US059-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	4

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:23:19

SAEID	USA-US059-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	4
Date of submission (Pre-filled from custom function)	14/OCT/2020 13:44
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

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:23:19

SAEID	USA-US059-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	4
Date of submission (Pre-filled from custom function)	19/OCT/2020 16:55
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

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:23:19

SAEID	USA-US059-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	4
Date of submission (Pre-filled from custom function)	30/OCT/2020 15:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:23:19

SAEID	USA-US059-2020-MRNA-1273-P301000006
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	4
Date of submission (Pre-filled from custom function)	12/NOV/2020 14:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3402042 (Prod: Meridian Clinical Research, LLC)

US3402042

Form: Participant Creation

Generated On: 26 Nov 2020 09:23:19

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3402042'	RWS_ENDPOINT ENDPOINT (b) (4) 	28 Jul 2020 14:04:22

US3402042

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:05:34

US3402042

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '28 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	28 Jul 2020 14:04:23

US3402042

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:05:34

US3402042

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	28 Jul 2020 15:05:34

US3402042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered (b) (6) 1948'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Jul 2020 14:04:24

US3402042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:19

[Age](#)

Audit	User	Time (GMT)
User entered '72'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:19

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:19

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '72'	System	28 Jul 2020 15:06:23

US3402042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:19

Sex

Audit	User	Time (GMT)
User entered 'Male (M)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:19

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:19

White

Audit	User	Time (GMT)
User entered '1'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:19

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:19

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:19

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:19

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:19

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:19

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:19

Unknown

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:19

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:06

US3402042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '28 Jul 2020'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:23

US3402042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	28 Jul 2020 15:06:23

US3402042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '2020'	System	28 Jul 2020 15:06:23

US3402042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:19

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:23

US3402042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:23

US3402042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:23

US3402042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:19

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:23

US3402042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:19

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:23

US3402042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:19

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Jul 2020 14:04:23

US3402042

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:19

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jul 2020 15:06:31

US3402042

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:06:31

US3402042

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:23:19

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:24:24

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:19

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of MH #7 PULMONARY HYPERTENSION (UN UNK 2000-Ongoing). If yes, please ensure only one entry is recorded. Otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 10:17:51
Query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of MH #7 PULMONARY HYPERTENSION (UN UNK 2000-Ongoing). If yes, please ensure only one entry is recorded. Otherwise, please clarify.' answered with 'THIS IS OT PULMONARY HYPERTENSION' (Site from DM).	Jennifer Molstead (b) (4)	26 Sep 2020 14:12:30
User opened query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of MH #7 PULMONARY HYPERTENSION (UN UNK 2000-Ongoing). If yes, please ensure only one entry is recorded. Otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 18:05:45
User coded data point as SOC: Vascular disorders, HLG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:34
Data point term sent to Coder	System	29 Jul 2020 13:27:45
User entered 'HYPERTENSION'	Tarin Gordon (b) (4)	29 Jul 2020 13:27:13

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2000'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:27:13

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:27:13

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:27:13

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:27:13

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:27:13

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	29 Jul 2020 13:27:13

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '2000'	System	29 Jul 2020 13:27:13

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 13:27:13

US3402042

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 13:27:13

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:19

[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)	03 Aug 2020 21:40:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:40:30
Data point term sent to Coder	System	29 Jul 2020 13:27:46
User entered 'BENIGN PROSTATIC HYPERTROPHY'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:27:44

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 1992'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:27:44

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:27:44

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:27:44

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:27:44

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:27:44

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Jan 1992'	System	29 Jul 2020 13:27:44

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '1992'	System	29 Jul 2020 13:27:44

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 13:27:44

US3402042

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 13:27:44

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:40
Data point term sent to Coder	System	29 Jul 2020 13:41:53
User entered 'PULMONARY EMBOLISM'	Tarin Gordon (b) (4)	29 Jul 2020 13:41:28

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:41:28

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:41:28

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:41:28

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:41:28

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:41:28

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	29 Jul 2020 13:41:28

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '2018'	System	29 Jul 2020 13:41:28

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 13:41:28

US3402042

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 13:41:28

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:19

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis leg - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:57:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 21:57:11
Data point term sent to Coder	System	29 Jul 2020 13:42:55
User entered 'DEEP VEIN THROMBOSIS, RIGHT LEG'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:42:07

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:42:07

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:42:07

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:42:07

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:42:07

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:42:07

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	29 Jul 2020 13:42:07

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '2018'	System	29 Jul 2020 13:42:07

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 13:42:07

US3402042

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 13:42:07

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 12:31:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 12:31:14
Data point term sent to Coder	System	03 Aug 2020 21:50:52
Datapoint queued for coding (5007943).	System	03 Aug 2020 21:49:54
User entered 'UTICARIA' reason for change: Data Entry Error	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:43:02
Data point term sent to Coder	System	29 Jul 2020 13:42:55
User entered 'URTICARIA'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:42:41

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 1967'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:42:41

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:42:41

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:42:41

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:42:41

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:42:41

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Jan 1967'	System	29 Jul 2020 13:42:41

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '1967'	System	29 Jul 2020 13:42:41

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 13:42:41

US3402042

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 13:42:41

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:41
Data point term sent to Coder	System	29 Jul 2020 13:43:55
User entered 'PNEUMONIA'	Tarin Gordon (b) (4)	29 Jul 2020 13:43:23
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:43:23

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:43:23

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:43:23

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:43:23

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:43:23

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	29 Jul 2020 13:43:23

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '2016'	System	29 Jul 2020 13:43:23

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	29 Jul 2020 13:43:23

US3402042

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '2016'	System	29 Jul 2020 13:43:23

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:30
Data point term sent to Coder	System	29 Jul 2020 13:44:56
User entered 'HIATAL HERNIA'	Tarin Gordon (b) (4)	29 Jul 2020 13:44:02
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 1990'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:44:02

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:44:02

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:44:02

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:44:02

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:44:02

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	29 Jul 2020 13:44:02

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '1990'	System	29 Jul 2020 13:44:02

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 13:44:02

US3402042

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 13:44:02

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:41:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:41:04
Data point term sent to Coder	System	29 Jul 2020 13:44:58
User entered 'DEPRESSION'	Tarin Gordon (b) (4)	29 Jul 2020 13:44:17
	(b) (4)	

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:44:17

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:44:17

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:44:17

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:44:17

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:44:17

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	29 Jul 2020 13:44:17

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '2010'	System	29 Jul 2020 13:44:17

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 13:44:17

US3402042

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 13:44:17

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:39
Data point term sent to Coder	System	29 Jul 2020 13:44:58
User entered 'IRRITABLE BOWEL SYNDROME'	Tarin Gordon (b) (4)	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '2010'	System	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 13:44:38

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:23:19

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 19:48:25
Query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'UPDATED' (Site from DM).	Jennifer Molstead (b) (4)	26 Sep 2020 13:58:04
User opened query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 18:06:52
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Emphysema - version MedDRA\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:25
Data point term sent to Coder	System	29 Jul 2020 13:50:04
User entered 'EMPHYSEMA'	Tarin Gordon (b) (4)	29 Jul 2020 13:49:32

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2000'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:49:32

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:49:32

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:23:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:49:32

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:49:32

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:23:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:49:32

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	29 Jul 2020 13:49:32

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '2000'	System	29 Jul 2020 13:49:32

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 13:49:32

US3402042

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 13:49:32

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:23:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:04:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:04:07
Data point term sent to Coder	System	05 Oct 2020 16:02:52
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Traci Hull (b) (4)	05 Oct 2020 16:02:13

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 1990'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:02:13

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:02:13

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:23:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:02:13

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:02:13

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:23:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:02:13

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	05 Oct 2020 16:02:13

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '1990'	System	05 Oct 2020 16:02:13

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:02:13

US3402042

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:02:13

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Jul 2020'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '09:30'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '28 Jul 2020 09:30'	System	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '165' cm	Tarin Gordon (b) (4)	29 Jul 2020 13:50:39
DataPoint set to visible.	(b) (4) System	28 Jul 2020 15:06:31

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '60.8' kg	Tarin Gordon (b) (4)	29 Jul 2020 13:50:39
DataPoint set to visible.	(b) (4) System	28 Jul 2020 15:06:31

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '22.33242'	System	16 Sep 2020 23:37:15
User entered '22.3'	System	29 Jul 2020 13:50:39
DataPoint set to visible.	System	28 Jul 2020 15:06:31

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	29 Jul 2020 13:50:39
DataPoint set to visible.	System	28 Jul 2020 15:06:31

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '16'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '108'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '64'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Jul 2020 13:50:39

US3402042

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:50:46

US3402042

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:19

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)	27 Aug 2020 13:12:20
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		25 Aug 2020 15:23:19
User entered '28 Jul 2020'	Tarin Gordon (b) (4)	29 Jul 2020 13:50:46

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

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)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

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)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

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)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

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)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

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)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

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'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

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'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '1'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:19

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:17

US3402042

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:31

US3402042

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '28 Jul 2020'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:31

US3402042

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:31

US3402042

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	29 Jul 2020 13:51:31

US3402042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '28 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	28 Jul 2020 14:04:26

US3402042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:19

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 01:06:38
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:06:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Jul 2020 14:04:26
User entered '184073' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Jul 2020 14:04:26

US3402042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	28 Jul 2020 14:04:26

US3402042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:19

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 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:59

US3402042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:59

US3402042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:59

US3402042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:19

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:59

US3402042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:19

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:51:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:19

Height

Audit	User	Time (GMT)
User entered '165' cm	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:19

Weight

Audit	User	Time (GMT)
User entered '60.8' kg	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:19

Height

Audit	User	Time (GMT)
User entered '165' cm	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:19

Weight

Audit	User	Time (GMT)
User entered '60.8' kg	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Jul 2020'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '09:30'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '28 Jul 2020 09:30'	System	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '16'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '108'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '64'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:19

Height

Audit	User	Time (GMT)
User entered '165' cm	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:19

Weight

Audit	User	Time (GMT)
User entered '60.8' kg	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Jul 2020'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

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)	14 Aug 2020 18:49:00
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30MIN' (Site from System).	Tarin Gordon (b) (4)	29 Jul 2020 13:54:10
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).		29 Jul 2020 13:53:59
User entered '11:28'	Tarin Gordon (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '28 Jul 2020 11:28'	System	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.1' F	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '16'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '106'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '68'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Jul 2020 13:53:59

US3402042

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:19

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:56:39

US3402042

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Jul 2020'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:56:39

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:07:15

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:07:15

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

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)	28 Jul 2020 15:07:15

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	28 Jul 2020 15:07:15

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Jul 2020'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:07:15

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '10:56'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:07:15

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '28 Jul 2020 10:56'	System	28 Jul 2020 15:07:15

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 15:07:15

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	28 Jul 2020 15:07:15

US3402042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	28 Jul 2020 15:07:15

US3402042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:57:01

US3402042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Jul 2020'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:57:01

US3402042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:32'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:57:01

US3402042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '28 Jul 2020 10:32'	System	29 Jul 2020 13:57:01

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Jul 2020'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:57:18

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:57:18

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:57:18

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:22'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:57:18

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '28 Jul 2020 10:22'	System	29 Jul 2020 13:57:18

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:57:18

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Tarin Gordon (b) (4)	29 Jul 2020 13:57:28
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	29 Jul 2020 13:57:18

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	29 Jul 2020 13:57:28
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	29 Jul 2020 13:57:28
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	29 Jul 2020 13:57:18
User entered empty.	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:57:18

US3402042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Jul 2020 13:57:18

US3402042

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	29 Jul 2020 13:57:41

US3402042

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 13:57:41

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:35:42', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2cf39b4d-eaaf-4389-9eb6-42002a2043d7'	System	28 Jul 2020 15:36:14
User entered 'Yes (Y)'	System	28 Jul 2020 15:36:14

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:35:52', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2cf39b4d-eaaf-4389-9eb6-42002a2043d7'	System	28 Jul 2020 15:36:14
User entered '97.1'	System	28 Jul 2020 15:36:14

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:36:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2cf39b4d-eaaf-4389-9eb6-42002a2043d7'	System	28 Jul 2020 15:36:14
User entered 'No (N)'	System	28 Jul 2020 15:36:14

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:36:11', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2cf39b4d-eaaf-4389-9eb6-42002a2043d7'	System	28 Jul 2020 15:36:14
User entered '28 Jul 2020 11:36'	System	28 Jul 2020 15:36:14

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 11:16'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 13:46'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T14:53:28', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8ac9097-ddd5-4f16-b861-094fc5289cba'	System	28 Jul 2020 18:54:09
User entered 'Yes (Y)'	System	28 Jul 2020 18:54:09

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T14:53:46', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8ac9097-ddd5-4f16-b861-094fc5289cba' User entered '97.3'	System	28 Jul 2020 18:54:09
	System	28 Jul 2020 18:54:09

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T14:53:54', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8ac9097-ddd5-4f16-b861-094fc5289cba'	System	28 Jul 2020 18:54:09
User entered 'No (N)'	System	28 Jul 2020 18:54:09

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T14:54:05', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8ac9097-ddd5-4f16-b861-094fc5289cba' User entered '28 Jul 2020 14:54'	System	28 Jul 2020 18:54:09
	System	28 Jul 2020 18:54:09

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 14:41'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 2'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:12:39', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '910a1aaa-ee5f-459c-a0f5-f34d225cec25'	System	29 Jul 2020 17:13:25
User entered 'Yes (Y)'	System	29 Jul 2020 17:13:25

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:13:05', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '910a1aaa-ee5f-459c-a0f5-f34d225cec25'	System	29 Jul 2020 17:13:25
User entered '98.3'	System	29 Jul 2020 17:13:25

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:13:19', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '910a1aaa-ee5f-459c-a0f5-f34d225cec25'	System	29 Jul 2020 17:13:25
User entered 'No (N)'	System	29 Jul 2020 17:13:25

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:13:22', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '910a1aaa-ee5f-459c-a0f5-f34d225cec25'	System	29 Jul 2020 17:13:25
User entered '29 Jul 2020 13:13'	System	29 Jul 2020 17:13:25

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 3'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:29:17', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '64f1ae9c-e480-4d41-a082-2bd01d885411'	System	30 Jul 2020 16:29:41
User entered 'Yes (Y)'	System	30 Jul 2020 16:29:41

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:29:28', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '64f1ae9c-e480-4d41-a082-2bd01d885411'	System	30 Jul 2020 16:29:41
User entered '97.3'	System	30 Jul 2020 16:29:41

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:29:33', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '64f1ae9c-e480-4d41-a082-2bd01d885411'	System	30 Jul 2020 16:29:41
User entered 'No (N)'	System	30 Jul 2020 16:29:41

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:29:37', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '64f1ae9c-e480-4d41-a082-2bd01d885411'	System	30 Jul 2020 16:29:41
User entered '30 Jul 2020 12:29'	System	30 Jul 2020 16:29:41

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 4'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '217560dc-8e0c-4ddb-836e-9bedebfcd447'	System	31 Jul 2020 16:14:24
User entered 'Yes (Y)'	System	31 Jul 2020 16:14:24

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:19

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:11', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '217560dc-8e0c-4ddb-836e-9bedebfcd447'	System	31 Jul 2020 16:14:24
User entered '97.0'	System	31 Jul 2020 16:14:24

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:16', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '217560dc-8e0c-4ddb-836e-9bedebfcd447'	System	31 Jul 2020 16:14:24
User entered 'No (N)'	System	31 Jul 2020 16:14:24

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:20', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '217560dc-8e0c-4ddb-836e-9bedebfcd447'	System	31 Jul 2020 16:14:24
User entered '31 Jul 2020 12:14'	System	31 Jul 2020 16:14:24

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 5'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:08:35', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5ee71f84-0638-4c72-a664-50b115216f9d'	System	01 Aug 2020 16:08:51
User entered 'Yes (Y)'	System	01 Aug 2020 16:08:51

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:19

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:08:42', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5ee71f84-0638-4c72-a664-50b115216f9d' User entered '97.3'	System	01 Aug 2020 16:08:51
	System	01 Aug 2020 16:08:51

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:08:45', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5ee71f84-0638-4c72-a664-50b115216f9d'	System	01 Aug 2020 16:08:51
User entered 'No (N)'	System	01 Aug 2020 16:08:51

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:08:49', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5ee71f84-0638-4c72-a664-50b115216f9d'	System	01 Aug 2020 16:08:51
User entered '01 Aug 2020 12:08'	System	01 Aug 2020 16:08:51

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 6'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:50:39', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '71c1550d-95eb-4c53-9d79-71ca8b582ac3'	System	03 Aug 2020 00:51:00
User entered 'Yes (Y)'	System	03 Aug 2020 00:51:00

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:50:46', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '71c1550d-95eb-4c53-9d79-71ca8b582ac3'	System	03 Aug 2020 00:51:00
User entered '97.3'	System	03 Aug 2020 00:51:00

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:50:51', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '71c1550d-95eb-4c53-9d79-71ca8b582ac3'	System	03 Aug 2020 00:51:00
User entered 'No (N)'	System	03 Aug 2020 00:51:00

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:50:56', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '71c1550d-95eb-4c53-9d79-71ca8b582ac3'	System	03 Aug 2020 00:51:00
User entered '02 Aug 2020 20:50'	System	03 Aug 2020 00:51:00

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 7'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:07:25', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd9839b01-0b32-4c98-a066-a260e69cfa78'	System	03 Aug 2020 16:07:49
User entered 'Yes (Y)'	System	03 Aug 2020 16:07:49

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:07:38', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd9839b01-0b32-4c98-a066-a260e69cfa78'	System	03 Aug 2020 16:07:49
User entered '97.4'	System	03 Aug 2020 16:07:49

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:07:42', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd9839b01-0b32-4c98-a066-a260e69cfa78'	System	03 Aug 2020 16:07:49
User entered 'No (N)'	System	03 Aug 2020 16:07:49

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:07:45', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd9839b01-0b32-4c98-a066-a260e69cfa78'	System	03 Aug 2020 16:07:49
User entered '03 Aug 2020 12:07'	System	03 Aug 2020 16:07:49

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:36:26', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '64a90276-3136-433f-9536-7a68222b563d'	System	28 Jul 2020 15:36:51
User entered 'None (1)'	System	28 Jul 2020 15:36:51

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:36:34', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '64a90276-3136-433f-9536-7a68222b563d'	System	28 Jul 2020 15:36:51
User entered 'No (N)'	System	28 Jul 2020 15:36:51

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:36:40', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '64a90276-3136-433f-9536-7a68222b563d'	System	28 Jul 2020 15:36:51
User entered 'No (N)'	System	28 Jul 2020 15:36:51

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:36:44', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '64a90276-3136-433f-9536-7a68222b563d'	System	28 Jul 2020 15:36:51
User entered 'None (1)'	System	28 Jul 2020 15:36:51

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:36:48', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '64a90276-3136-433f-9536-7a68222b563d'	System	28 Jul 2020 15:36:51
User entered '28 Jul 2020 11:36'	System	28 Jul 2020 15:36:51

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 11:16'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 13:46'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T14:54:33', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b53fbddb-bde6-402d-9335-23b0195f7265'	System	28 Jul 2020 19:01:53
User entered 'Does not interfere with activity (2)'	System	28 Jul 2020 19:01:53

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T14:54:38', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b53fbddb-bde6-402d-9335-23b0195f7265'	System	28 Jul 2020 19:01:53
User entered 'No (N)'	System	28 Jul 2020 19:01:53

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T14:58:27', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b53fbddb-bde6-402d-9335-23b0195f7265'	System	28 Jul 2020 19:01:53
User entered 'Yes (Y)'	System	28 Jul 2020 19:01:53

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:01:43', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b53fbddb-bde6-402d-9335-23b0195f7265' User entered '20'	System	28 Jul 2020 19:01:53

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T14:59:07', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b53fbddb-bde6-402d-9335-23b0195f7265'	System	28 Jul 2020 19:01:53
User entered 'None (1)'	System	28 Jul 2020 19:01:53

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:01:48', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b53fbddb-bde6-402d-9335-23b0195f7265'	System	28 Jul 2020 19:01:53
User entered '28 Jul 2020 15:01'	System	28 Jul 2020 19:01:53

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 14:41'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 2'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:13:53', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'faf5a06e-dd30-4b21-be51-e9323e36ff54'	System	29 Jul 2020 17:14:33
User entered 'Does not interfere with activity (2)'	System	29 Jul 2020 17:14:33

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:13:58', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'faf5a06e-dd30-4b21-be51-e9323e36ff54'	System	29 Jul 2020 17:14:33
User entered 'No (N)'	System	29 Jul 2020 17:14:33

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:14:01', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'faf5a06e-dd30-4b21-be51-e9323e36ff54'	System	29 Jul 2020 17:14:33
User entered 'Yes (Y)'	System	29 Jul 2020 17:14:33

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:19

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:14:13', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'faf5a06e-dd30-4b21-be51-e9323e36ff54' User entered '500'	System	29 Jul 2020 17:14:33
	System	29 Jul 2020 17:14:33

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:14:22', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'faf5a06e-dd30-4b21-be51-e9323e36ff54'	System	29 Jul 2020 17:14:33
User entered 'None (1)'	System	29 Jul 2020 17:14:33

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:14:30', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'faf5a06e-dd30-4b21-be51-e9323e36ff54'	System	29 Jul 2020 17:14:33
User entered '29 Jul 2020 13:14'	System	29 Jul 2020 17:14:33

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 3'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:29:48', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8f97f26-2aa2-456a-89c7-4d666695631d'	System	30 Jul 2020 16:30:20
User entered 'Does not interfere with activity (2)'	System	30 Jul 2020 16:30:20

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:29:52', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8f97f26-2aa2-456a-89c7-4d666695631d'	System	30 Jul 2020 16:30:20
User entered 'No (N)'	System	30 Jul 2020 16:30:20

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:29:57', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8f97f26-2aa2-456a-89c7-4d666695631d'	System	30 Jul 2020 16:30:20
User entered 'Yes (Y)'	System	30 Jul 2020 16:30:20

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:19

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:30:04', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8f97f26-2aa2-456a-89c7-4d666695631d' User entered '200'	System	30 Jul 2020 16:30:20
	System	30 Jul 2020 16:30:20

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:30:13', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8f97f26-2aa2-456a-89c7-4d666695631d'	System	30 Jul 2020 16:30:20
User entered 'None (1)'	System	30 Jul 2020 16:30:20

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:30:17', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd8f97f26-2aa2-456a-89c7-4d666695631d'	System	30 Jul 2020 16:30:20
User entered '30 Jul 2020 12:30'	System	30 Jul 2020 16:30:20

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 4'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:26', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3ce8ac39-ee8c-42f5-a56c-a23aa275ac9f'	System	31 Jul 2020 16:14:47
User entered 'None (1)'	System	31 Jul 2020 16:14:47

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:31', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3ce8ac39-ee8c-42f5-a56c-a23aa275ac9f'	System	31 Jul 2020 16:14:47
User entered 'No (N)'	System	31 Jul 2020 16:14:47

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:36', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3ce8ac39-ee8c-42f5-a56c-a23aa275ac9f'	System	31 Jul 2020 16:14:47
User entered 'No (N)'	System	31 Jul 2020 16:14:47

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:40', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3ce8ac39-ee8c-42f5-a56c-a23aa275ac9f'	System	31 Jul 2020 16:14:47
User entered 'None (1)'	System	31 Jul 2020 16:14:47

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:45', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3ce8ac39-ee8c-42f5-a56c-a23aa275ac9f' User entered '31 Jul 2020 12:14'	System	31 Jul 2020 16:14:47

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 5'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:08:53', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6c027440-a670-4398-a5a7-653a65efb964'	System	01 Aug 2020 16:09:23
User entered 'None (1)'	System	01 Aug 2020 16:09:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:08:57', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6c027440-a670-4398-a5a7-653a65efb964'	System	01 Aug 2020 16:09:23
User entered 'No (N)'	System	01 Aug 2020 16:09:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:09:05', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6c027440-a670-4398-a5a7-653a65efb964'	System	01 Aug 2020 16:09:23
User entered 'No (N)'	System	01 Aug 2020 16:09:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:09:15', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6c027440-a670-4398-a5a7-653a65efb964'	System	01 Aug 2020 16:09:23
User entered 'None (1)'	System	01 Aug 2020 16:09:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:09:21', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6c027440-a670-4398-a5a7-653a65efb964'	System	01 Aug 2020 16:09:23
User entered '01 Aug 2020 12:09'	System	01 Aug 2020 16:09:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 6'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:01', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bf719181-cf33-492a-8342-997b8f5509c9'	System	03 Aug 2020 00:51:23
User entered 'None (1)'	System	03 Aug 2020 00:51:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:09', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bf719181-cf33-492a-8342-997b8f5509c9'	System	03 Aug 2020 00:51:23
User entered 'No (N)'	System	03 Aug 2020 00:51:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:13', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bf719181-cf33-492a-8342-997b8f5509c9'	System	03 Aug 2020 00:51:23
User entered 'No (N)'	System	03 Aug 2020 00:51:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:17', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bf719181-cf33-492a-8342-997b8f5509c9'	System	03 Aug 2020 00:51:23
User entered 'None (1)'	System	03 Aug 2020 00:51:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:21', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bf719181-cf33-492a-8342-997b8f5509c9'	System	03 Aug 2020 00:51:23
User entered '02 Aug 2020 20:51'	System	03 Aug 2020 00:51:23

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 7'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:07:50', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f55dbb0c-1dfe-4df1-b88d-6fac4ac7ae82'	System	03 Aug 2020 16:08:08
User entered 'None (1)'	System	03 Aug 2020 16:08:08

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:07:55', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f55dbb0c-1dfe-4df1-b88d-6fac4ac7ae82'	System	03 Aug 2020 16:08:08
User entered 'No (N)'	System	03 Aug 2020 16:08:08

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:07:59', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f55dbb0c-1dfe-4df1-b88d-6fac4ac7ae82'	System	03 Aug 2020 16:08:08
User entered 'No (N)'	System	03 Aug 2020 16:08:08

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:03', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f55dbb0c-1dfe-4df1-b88d-6fac4ac7ae82'	System	03 Aug 2020 16:08:08
User entered 'None (1)'	System	03 Aug 2020 16:08:08

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:06', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f55dbb0c-1dfe-4df1-b88d-6fac4ac7ae82'	System	03 Aug 2020 16:08:08
User entered '03 Aug 2020 12:08'	System	03 Aug 2020 16:08:08

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:36:56', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3f8a8f3b-23ee-4ec9-842d-32a2a891f6f6'	System	28 Jul 2020 15:37:32
User entered 'None (0)'	System	28 Jul 2020 15:37:32

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:36:59', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3f8a8f3b-23ee-4ec9-842d-32a2a891f6f6'	System	28 Jul 2020 15:37:32
User entered 'None (0)'	System	28 Jul 2020 15:37:32

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:37:03', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3f8a8f3b-23ee-4ec9-842d-32a2a891f6f6'	System	28 Jul 2020 15:37:32
User entered 'None (0)'	System	28 Jul 2020 15:37:32

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:37:07', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3f8a8f3b-23ee-4ec9-842d-32a2a891f6f6'	System	28 Jul 2020 15:37:32
User entered 'None (0)'	System	28 Jul 2020 15:37:32

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:37:13', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3f8a8f3b-23ee-4ec9-842d-32a2a891f6f6'	System	28 Jul 2020 15:37:32
User entered 'None (0)'	System	28 Jul 2020 15:37:32

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:37:16', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3f8a8f3b-23ee-4ec9-842d-32a2a891f6f6'	System	28 Jul 2020 15:37:32
User entered 'None (0)'	System	28 Jul 2020 15:37:32

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:37:24', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3f8a8f3b-23ee-4ec9-842d-32a2a891f6f6'	System	28 Jul 2020 15:37:32
User entered 'No (N)'	System	28 Jul 2020 15:37:32

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T11:37:31', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3f8a8f3b-23ee-4ec9-842d-32a2a891f6f6'	System	28 Jul 2020 15:37:32
User entered '28 Jul 2020 11:37'	System	28 Jul 2020 15:37:32

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 11:16'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 13:46'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:01:56', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '862d00e0-52ed-4d1f-b630-a08c5e56734d'	System	28 Jul 2020 19:02:29
User entered 'None (0)'	System	28 Jul 2020 19:02:29

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:02:04', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '862d00e0-52ed-4d1f-b630-a08c5e56734d'	System	28 Jul 2020 19:02:29
User entered 'No interference with activity (1)'	System	28 Jul 2020 19:02:29

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:02:08', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '862d00e0-52ed-4d1f-b630-a08c5e56734d'	System	28 Jul 2020 19:02:29
User entered 'None (0)'	System	28 Jul 2020 19:02:29

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:02:12', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '862d00e0-52ed-4d1f-b630-a08c5e56734d'	System	28 Jul 2020 19:02:29
User entered 'None (0)'	System	28 Jul 2020 19:02:29

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:02:15', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '862d00e0-52ed-4d1f-b630-a08c5e56734d'	System	28 Jul 2020 19:02:29
User entered 'None (0)'	System	28 Jul 2020 19:02:29

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:02:19', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '862d00e0-52ed-4d1f-b630-a08c5e56734d'	System	28 Jul 2020 19:02:29
User entered 'None (0)'	System	28 Jul 2020 19:02:29

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:02:25', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '862d00e0-52ed-4d1f-b630-a08c5e56734d'	System	28 Jul 2020 19:02:29
User entered 'No (N)'	System	28 Jul 2020 19:02:29

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-28T15:02:28', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '862d00e0-52ed-4d1f-b630-a08c5e56734d'	System	28 Jul 2020 19:02:29
User entered '28 Jul 2020 15:02'	System	28 Jul 2020 19:02:29

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 14:41'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 2'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:14:35', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f22165f6-ce28-4acc-823b-2b42f49f6500'	System	29 Jul 2020 17:15:20
User entered 'None (0)'	System	29 Jul 2020 17:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:14:40', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f22165f6-ce28-4acc-823b-2b42f49f6500'	System	29 Jul 2020 17:15:20
User entered 'No interference with activity (1)'	System	29 Jul 2020 17:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:14:45', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f22165f6-ce28-4acc-823b-2b42f49f6500'	System	29 Jul 2020 17:15:20
User entered 'No interference with activity (1)'	System	29 Jul 2020 17:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:14:52', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f22165f6-ce28-4acc-823b-2b42f49f6500'	System	29 Jul 2020 17:15:20
User entered 'None (0)'	System	29 Jul 2020 17:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:14:55', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f22165f6-ce28-4acc-823b-2b42f49f6500'	System	29 Jul 2020 17:15:20
User entered 'None (0)'	System	29 Jul 2020 17:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:15:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f22165f6-ce28-4acc-823b-2b42f49f6500'	System	29 Jul 2020 17:15:20
User entered 'No interference with activity (1)'	System	29 Jul 2020 17:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:15:14', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f22165f6-ce28-4acc-823b-2b42f49f6500'	System	29 Jul 2020 17:15:20
User entered 'No (N)'	System	29 Jul 2020 17:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-29T13:15:18', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f22165f6-ce28-4acc-823b-2b42f49f6500'	System	29 Jul 2020 17:15:20
User entered '29 Jul 2020 13:15'	System	29 Jul 2020 17:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 3'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:30:23', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2b7da2a5-a3da-496c-938a-3fa05a71f083'	System	30 Jul 2020 16:31:06
User entered 'None (0)'	System	30 Jul 2020 16:31:06

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:30:29', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2b7da2a5-a3da-496c-938a-3fa05a71f083'	System	30 Jul 2020 16:31:06
User entered 'None (0)'	System	30 Jul 2020 16:31:06

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:30:33', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2b7da2a5-a3da-496c-938a-3fa05a71f083'	System	30 Jul 2020 16:31:06
User entered 'None (0)'	System	30 Jul 2020 16:31:06

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:30:38', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2b7da2a5-a3da-496c-938a-3fa05a71f083'	System	30 Jul 2020 16:31:06
User entered 'None (0)'	System	30 Jul 2020 16:31:06

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:30:45', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2b7da2a5-a3da-496c-938a-3fa05a71f083'	System	30 Jul 2020 16:31:06
User entered 'None (0)'	System	30 Jul 2020 16:31:06

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:30:49', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2b7da2a5-a3da-496c-938a-3fa05a71f083'	System	30 Jul 2020 16:31:06
User entered 'None (0)'	System	30 Jul 2020 16:31:06

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:31:01', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2b7da2a5-a3da-496c-938a-3fa05a71f083'	System	30 Jul 2020 16:31:06
User entered 'No (N)'	System	30 Jul 2020 16:31:06

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-30T12:31:05', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2b7da2a5-a3da-496c-938a-3fa05a71f083'	System	30 Jul 2020 16:31:06
User entered '30 Jul 2020 12:31'	System	30 Jul 2020 16:31:06

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 4'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:50', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3abbdeb8-9738-4bed-a5e8-dd043e9c8a4e'	System	31 Jul 2020 16:15:20
User entered 'None (0)'	System	31 Jul 2020 16:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:54', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3abbdeb8-9738-4bed-a5e8-dd043e9c8a4e'	System	31 Jul 2020 16:15:20
User entered 'None (0)'	System	31 Jul 2020 16:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:14:57', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3abbdeb8-9738-4bed-a5e8-dd043e9c8a4e'	System	31 Jul 2020 16:15:20
User entered 'None (0)'	System	31 Jul 2020 16:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:15:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3abbdeb8-9738-4bed-a5e8-dd043e9c8a4e'	System	31 Jul 2020 16:15:20
User entered 'None (0)'	System	31 Jul 2020 16:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:15:04', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3abbdeb8-9738-4bed-a5e8-dd043e9c8a4e'	System	31 Jul 2020 16:15:20
User entered 'None (0)'	System	31 Jul 2020 16:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:15:11', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3abbdeb8-9738-4bed-a5e8-dd043e9c8a4e'	System	31 Jul 2020 16:15:20
User entered 'None (0)'	System	31 Jul 2020 16:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:15:16', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3abbdeb8-9738-4bed-a5e8-dd043e9c8a4e'	System	31 Jul 2020 16:15:20
User entered 'No (N)'	System	31 Jul 2020 16:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-07-31T12:15:19', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3abbdeb8-9738-4bed-a5e8-dd043e9c8a4e' User entered '31 Jul 2020 12:15'	System	31 Jul 2020 16:15:20
	System	31 Jul 2020 16:15:20

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 5'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:09:27', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b444f4ff-6979-445a-89c2-d516bba3f83a'	System	01 Aug 2020 16:10:05
User entered 'None (0)'	System	01 Aug 2020 16:10:05

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:09:32', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b444f4ff-6979-445a-89c2-d516bba3f83a'	System	01 Aug 2020 16:10:05
User entered 'Significant; prevents daily activity (3)'	System	01 Aug 2020 16:10:05

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:09:35', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b444f4ff-6979-445a-89c2-d516bba3f83a'	System	01 Aug 2020 16:10:05
User entered 'Some interference with activity (2)'	System	01 Aug 2020 16:10:05

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:09:37', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b444f4ff-6979-445a-89c2-d516bba3f83a'	System	01 Aug 2020 16:10:05
User entered 'None (0)'	System	01 Aug 2020 16:10:05

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:09:41', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b444f4ff-6979-445a-89c2-d516bba3f83a'	System	01 Aug 2020 16:10:05
User entered 'None (0)'	System	01 Aug 2020 16:10:05

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:09:50', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b444f4ff-6979-445a-89c2-d516bba3f83a'	System	01 Aug 2020 16:10:05
User entered 'None (0)'	System	01 Aug 2020 16:10:05

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:10:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b444f4ff-6979-445a-89c2-d516bba3f83a'	System	01 Aug 2020 16:10:05
User entered 'No (N)'	System	01 Aug 2020 16:10:05

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-01T12:10:03', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b444f4ff-6979-445a-89c2-d516bba3f83a'	System	01 Aug 2020 16:10:05
User entered '01 Aug 2020 12:10'	System	01 Aug 2020 16:10:05

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 6'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:28', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c322a6c9-7086-4942-9fc7-1baedc0f03e9'	System	03 Aug 2020 00:51:57
User entered 'None (0)'	System	03 Aug 2020 00:51:57

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:31', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c322a6c9-7086-4942-9fc7-1baedc0f03e9'	System	03 Aug 2020 00:51:57
User entered 'None (0)'	System	03 Aug 2020 00:51:57

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:33', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c322a6c9-7086-4942-9fc7-1baedc0f03e9'	System	03 Aug 2020 00:51:57
User entered 'None (0)'	System	03 Aug 2020 00:51:57

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:36', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c322a6c9-7086-4942-9fc7-1baedc0f03e9'	System	03 Aug 2020 00:51:57
User entered 'None (0)'	System	03 Aug 2020 00:51:57

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:42', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c322a6c9-7086-4942-9fc7-1baedc0f03e9'	System	03 Aug 2020 00:51:57
User entered 'None (0)'	System	03 Aug 2020 00:51:57

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:46', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c322a6c9-7086-4942-9fc7-1baedc0f03e9'	System	03 Aug 2020 00:51:57
User entered 'None (0)'	System	03 Aug 2020 00:51:57

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:52', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c322a6c9-7086-4942-9fc7-1baedc0f03e9'	System	03 Aug 2020 00:51:57
User entered 'No (N)'	System	03 Aug 2020 00:51:57

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-02T20:51:54', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c322a6c9-7086-4942-9fc7-1baedc0f03e9'	System	03 Aug 2020 00:51:57
User entered '02 Aug 2020 20:51'	System	03 Aug 2020 00:51:57

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 7'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:11', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bc6648d9-28e4-4a48-a5a5-e2f845310a42'	System	03 Aug 2020 16:08:40
User entered 'None (0)'	System	03 Aug 2020 16:08:40

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:16', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bc6648d9-28e4-4a48-a5a5-e2f845310a42'	System	03 Aug 2020 16:08:40
User entered 'None (0)'	System	03 Aug 2020 16:08:40

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:20', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bc6648d9-28e4-4a48-a5a5-e2f845310a42'	System	03 Aug 2020 16:08:40
User entered 'None (0)'	System	03 Aug 2020 16:08:40

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:23', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bc6648d9-28e4-4a48-a5a5-e2f845310a42'	System	03 Aug 2020 16:08:40
User entered 'None (0)'	System	03 Aug 2020 16:08:40

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:27', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bc6648d9-28e4-4a48-a5a5-e2f845310a42'	System	03 Aug 2020 16:08:40
User entered 'None (0)'	System	03 Aug 2020 16:08:40

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:30', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bc6648d9-28e4-4a48-a5a5-e2f845310a42'	System	03 Aug 2020 16:08:40
User entered 'None (0)'	System	03 Aug 2020 16:08:40

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:35', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bc6648d9-28e4-4a48-a5a5-e2f845310a42'	System	03 Aug 2020 16:08:40
User entered 'No (N)'	System	03 Aug 2020 16:08:40

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-03T12:08:38', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'bc6648d9-28e4-4a48-a5a5-e2f845310a42'	System	03 Aug 2020 16:08:40
User entered '03 Aug 2020 12:08'	System	03 Aug 2020 16:08:40

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	28 Jul 2020 15:07:15

US3402042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Aug 2020 18:34:11

US3402042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '04 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:09:44
User entered '4 Aug 2020'	Traci Hull (b) (4)	11 Aug 2020 18:34:11

US3402042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[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)	11 Aug 2020 18:34:11

US3402042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Aug 2020 18:34:11

US3402042

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Aug 2020 18:34:45

US3402042

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 18:34:45

US3402042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Aug 2020 18:34:57

US3402042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Traci Hull (b) (4) (b) (4)	11 Aug 2020 18:34:57

US3402042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[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)	11 Aug 2020 18:34:57

US3402042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Aug 2020 18:34:57

US3402042

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Aug 2020 18:35:11

US3402042

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 18:35:11

US3402042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Aug 2020 12:16:53

US3402042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Traci Hull (b) (4) (b) (4)	19 Aug 2020 12:16:53

US3402042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[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)	19 Aug 2020 12:16:53

US3402042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Aug 2020 12:16:53

US3402042

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Traci Hull (b) (4)	26 Aug 2020 12:48:08
User entered 'No (N)' reason for change: Data Entry Error	Traci Hull (b) (4)	26 Aug 2020 12:48:04
User entered 'Yes (Y)'	Traci Hull (b) (4)	19 Aug 2020 12:17:03

US3402042

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 12:48:08
User entered empty.	System	26 Aug 2020 12:48:04
User entered '1'	System	19 Aug 2020 12:17:03

US3402042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:23:19

US3402042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:23:19

US3402042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

[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)	25 Aug 2020 15:23:19

US3402042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	25 Aug 2020 15:23:19

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '09:10'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '25 Aug 2020 09:10'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '15'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '110'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '72'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '10:44'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '25 Aug 2020 10:44'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '72'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '15'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '110'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '72'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 15:24:32

US3402042

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:40

US3402042

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:40

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Abigail Wine (b) (4) (b) (4)	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	Abigail Wine (b) (4) (b) (4)	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Abigail Wine (b) (4) (b) (4)	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '10:14'	Abigail Wine (b) (4) (b) (4)	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '25 Aug 2020 10:14'	System	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	Abigail Wine (b) (4) (b) (4)	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 14:21:30

US3402042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:59

US3402042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:59

US3402042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '09:47'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:24:59

US3402042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '25 Aug 2020 09:47'	System	25 Aug 2020 15:24:59

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 12:48:35

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 12:48:35

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 12:48:35

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '09:50'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 12:48:35

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '25 Aug 2020 09:50'	System	26 Aug 2020 12:48:35

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 12:48:35

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	26 Aug 2020 12:48:35

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	26 Aug 2020 12:48:35

US3402042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 12:48:35

US3402042

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 15:25:05

US3402042

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:25:05

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:46:45', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c34cd6aa-ae51-4e84-aa17-e49822ebc4a0'	System	25 Aug 2020 14:47:19
User entered 'Yes (Y)'	System	25 Aug 2020 14:47:19

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:46:52', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c34cd6aa-ae51-4e84-aa17-e49822ebc4a0' User entered '97.7'	System	25 Aug 2020 14:47:19

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:47:11', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c34cd6aa-ae51-4e84-aa17-e49822ebc4a0'	System	25 Aug 2020 14:47:19
User entered 'No (N)'	System	25 Aug 2020 14:47:19

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:47:17', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'c34cd6aa-ae51-4e84-aa17-e49822ebc4a0'	System	25 Aug 2020 14:47:19
User entered '25 Aug 2020 10:47'	System	25 Aug 2020 14:47:19

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 10:34'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 13:04'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:51:34', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '405f692b-2561-4d50-849d-32ac3e435ca1'	System	25 Aug 2020 20:51:59
User entered 'Yes (Y)'	System	25 Aug 2020 20:51:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:51:46', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '405f692b-2561-4d50-849d-32ac3e435ca1'	System	25 Aug 2020 20:51:59
User entered '99.5'	System	25 Aug 2020 20:51:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:51:51', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '405f692b-2561-4d50-849d-32ac3e435ca1'	System	25 Aug 2020 20:51:59
User entered 'No (N)'	System	25 Aug 2020 20:51:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:51:57', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '405f692b-2561-4d50-849d-32ac3e435ca1'	System	25 Aug 2020 20:51:59
User entered '25 Aug 2020 16:51'	System	25 Aug 2020 20:51:59

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 13:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 2'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:11:35', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '14cedc76-e3bd-4e49-9522-acb49627c68d'	System	26 Aug 2020 16:11:55
User entered 'Yes (Y)'	System	26 Aug 2020 16:11:55

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:11:45', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '14cedc76-e3bd-4e49-9522-acb49627c68d' User entered '95.9'	System	26 Aug 2020 16:11:55
	System	26 Aug 2020 16:11:55

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:11:49', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '14cedc76-e3bd-4e49-9522-acb49627c68d'	System	26 Aug 2020 16:11:55
User entered 'No (N)'	System	26 Aug 2020 16:11:55

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:11:53', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '14cedc76-e3bd-4e49-9522-acb49627c68d' User entered '26 Aug 2020 12:11'	System	26 Aug 2020 16:11:55
	System	26 Aug 2020 16:11:55

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 3'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:25:23', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'edb5e98f-14a9-4196-99a1-e0cee3bca037'	System	27 Aug 2020 16:25:42
User entered 'Yes (Y)'	System	27 Aug 2020 16:25:42

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:25:30', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'edb5e98f-14a9-4196-99a1-e0cee3bca037'	System	27 Aug 2020 16:25:42
User entered '97.6'	System	27 Aug 2020 16:25:42

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:25:34', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'edb5e98f-14a9-4196-99a1-e0cee3bca037'	System	27 Aug 2020 16:25:42
User entered 'No (N)'	System	27 Aug 2020 16:25:42

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:25:37', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'edb5e98f-14a9-4196-99a1-e0cee3bca037'	System	27 Aug 2020 16:25:42
User entered '27 Aug 2020 12:25'	System	27 Aug 2020 16:25:42

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 4'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:19:08', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8eaa6ca4-6398-4d09-96a5-5eee009a9de6'	System	28 Aug 2020 19:19:30
User entered 'Yes (Y)'	System	28 Aug 2020 19:19:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:19:19', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8eaa6ca4-6398-4d09-96a5-5eee009a9de6' User entered '97.2'	System	28 Aug 2020 19:19:30
	System	28 Aug 2020 19:19:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:19:25', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8eaa6ca4-6398-4d09-96a5-5eee009a9de6'	System	28 Aug 2020 19:19:30
User entered 'No (N)'	System	28 Aug 2020 19:19:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:19:29', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8eaa6ca4-6398-4d09-96a5-5eee009a9de6'	System	28 Aug 2020 19:19:30
User entered '28 Aug 2020 15:19'	System	28 Aug 2020 19:19:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 5'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:06', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '48974f71-8243-46e8-a6f1-f45276caa903'	System	29 Aug 2020 16:06:23
User entered 'Yes (Y)'	System	29 Aug 2020 16:06:23

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:13', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '48974f71-8243-46e8-a6f1-f45276caa903'	System	29 Aug 2020 16:06:23
User entered '97.2'	System	29 Aug 2020 16:06:23

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:17', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '48974f71-8243-46e8-a6f1-f45276caa903'	System	29 Aug 2020 16:06:23
User entered 'No (N)'	System	29 Aug 2020 16:06:23

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:20', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '48974f71-8243-46e8-a6f1-f45276caa903'	System	29 Aug 2020 16:06:23
User entered '29 Aug 2020 12:06'	System	29 Aug 2020 16:06:23

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 6'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:32:18', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd2e1c8a2-eaed-48fd-bc2e-587238d12d8a'	System	30 Aug 2020 19:32:48
User entered 'Yes (Y)'	System	30 Aug 2020 19:32:48

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:32:30', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd2e1c8a2-eaed-48fd-bc2e-587238d12d8a'	System	30 Aug 2020 19:32:48
User entered '97.5'	System	30 Aug 2020 19:32:48

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:32:42', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd2e1c8a2-eaed-48fd-bc2e-587238d12d8a'	System	30 Aug 2020 19:32:48
User entered 'No (N)'	System	30 Aug 2020 19:32:48

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:32:45', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'd2e1c8a2-eaed-48fd-bc2e-587238d12d8a'	System	30 Aug 2020 19:32:48
User entered '30 Aug 2020 15:32'	System	30 Aug 2020 19:32:48

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 7'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:02:58', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'eb4f5844-956e-4514-90f3-57568f1a1623'	System	31 Aug 2020 16:04:19
User entered 'Yes (Y)'	System	31 Aug 2020 16:04:19

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:06', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'eb4f5844-956e-4514-90f3-57568f1a1623'	System	31 Aug 2020 16:04:19
User entered '97.6'	System	31 Aug 2020 16:04:19

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:10', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'eb4f5844-956e-4514-90f3-57568f1a1623'	System	31 Aug 2020 16:04:19
User entered 'No (N)'	System	31 Aug 2020 16:04:19

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:18', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'eb4f5844-956e-4514-90f3-57568f1a1623'	System	31 Aug 2020 16:04:19
User entered '31 Aug 2020 12:03'	System	31 Aug 2020 16:04:19

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:47:25', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8f569fde-0259-47c7-bfce-03a05b3e50ea'	System	25 Aug 2020 14:47:49
User entered 'None (1)'	System	25 Aug 2020 14:47:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:47:29', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8f569fde-0259-47c7-bfce-03a05b3e50ea'	System	25 Aug 2020 14:47:49
User entered 'No (N)'	System	25 Aug 2020 14:47:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:47:35', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8f569fde-0259-47c7-bfce-03a05b3e50ea'	System	25 Aug 2020 14:47:49
User entered 'No (N)'	System	25 Aug 2020 14:47:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:47:40', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8f569fde-0259-47c7-bfce-03a05b3e50ea'	System	25 Aug 2020 14:47:49
User entered 'None (1)'	System	25 Aug 2020 14:47:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:47:48', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '8f569fde-0259-47c7-bfce-03a05b3e50ea'	System	25 Aug 2020 14:47:49
User entered '25 Aug 2020 10:47'	System	25 Aug 2020 14:47:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 10:34'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 13:04'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:10', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '7cde6293-6015-44a7-929b-956b234bb3cb'	System	25 Aug 2020 20:52:37
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 20:52:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:14', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '7cde6293-6015-44a7-929b-956b234bb3cb'	System	25 Aug 2020 20:52:37
User entered 'No (N)'	System	25 Aug 2020 20:52:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:23', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '7cde6293-6015-44a7-929b-956b234bb3cb'	System	25 Aug 2020 20:52:37
User entered 'No (N)'	System	25 Aug 2020 20:52:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:27', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '7cde6293-6015-44a7-929b-956b234bb3cb'	System	25 Aug 2020 20:52:37
User entered 'None (1)'	System	25 Aug 2020 20:52:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:31', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '7cde6293-6015-44a7-929b-956b234bb3cb'	System	25 Aug 2020 20:52:37
User entered '25 Aug 2020 16:52'	System	25 Aug 2020 20:52:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 13:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 2'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:12:02', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '404cebb3-74ae-47a1-9a64-ff93795a6061'	System	26 Aug 2020 16:12:37
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 16:12:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:12:06', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '404cebb3-74ae-47a1-9a64-ff93795a6061'	System	26 Aug 2020 16:12:37
User entered 'No (N)'	System	26 Aug 2020 16:12:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:12:29', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '404cebb3-74ae-47a1-9a64-ff93795a6061'	System	26 Aug 2020 16:12:37
User entered 'No (N)'	System	26 Aug 2020 16:12:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:12:33', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '404cebb3-74ae-47a1-9a64-ff93795a6061'	System	26 Aug 2020 16:12:37
User entered 'None (1)'	System	26 Aug 2020 16:12:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:12:36', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '404cebb3-74ae-47a1-9a64-ff93795a6061'	System	26 Aug 2020 16:12:37
User entered '26 Aug 2020 12:12'	System	26 Aug 2020 16:12:37

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 3'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:25:47', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '4a3c031f-9060-4075-bc01-efb78713bd37'	System	27 Aug 2020 16:26:25
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 16:26:25

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:25:51', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '4a3c031f-9060-4075-bc01-efb78713bd37'	System	27 Aug 2020 16:26:25
User entered 'No (N)'	System	27 Aug 2020 16:26:25

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:26:17', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '4a3c031f-9060-4075-bc01-efb78713bd37'	System	27 Aug 2020 16:26:25
User entered 'No (N)'	System	27 Aug 2020 16:26:25

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:26:20', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '4a3c031f-9060-4075-bc01-efb78713bd37'	System	27 Aug 2020 16:26:25
User entered 'None (1)'	System	27 Aug 2020 16:26:25

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:26:23', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '4a3c031f-9060-4075-bc01-efb78713bd37'	System	27 Aug 2020 16:26:25
User entered '27 Aug 2020 12:26'	System	27 Aug 2020 16:26:25

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 4'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:19:38', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '286c0813-62c4-42b3-9cd7-bbc2dee007b5'	System	28 Aug 2020 19:19:57
User entered 'None (1)'	System	28 Aug 2020 19:19:57

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:19:41', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '286c0813-62c4-42b3-9cd7-bbc2dee007b5'	System	28 Aug 2020 19:19:57
User entered 'No (N)'	System	28 Aug 2020 19:19:57

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:19:47', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '286c0813-62c4-42b3-9cd7-bbc2dee007b5'	System	28 Aug 2020 19:19:57
User entered 'No (N)'	System	28 Aug 2020 19:19:57

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:19:50', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '286c0813-62c4-42b3-9cd7-bbc2dee007b5'	System	28 Aug 2020 19:19:57
User entered 'None (1)'	System	28 Aug 2020 19:19:57

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:19:54', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '286c0813-62c4-42b3-9cd7-bbc2dee007b5'	System	28 Aug 2020 19:19:57
User entered '28 Aug 2020 15:19'	System	28 Aug 2020 19:19:57

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 5'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:29', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '042cf65f-275b-492b-9aa5-ef18753716dc'	System	29 Aug 2020 16:06:49
User entered 'None (1)'	System	29 Aug 2020 16:06:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:33', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '042cf65f-275b-492b-9aa5-ef18753716dc'	System	29 Aug 2020 16:06:49
User entered 'No (N)'	System	29 Aug 2020 16:06:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:37', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '042cf65f-275b-492b-9aa5-ef18753716dc'	System	29 Aug 2020 16:06:49
User entered 'No (N)'	System	29 Aug 2020 16:06:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:43', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '042cf65f-275b-492b-9aa5-ef18753716dc'	System	29 Aug 2020 16:06:49
User entered 'None (1)'	System	29 Aug 2020 16:06:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:47', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '042cf65f-275b-492b-9aa5-ef18753716dc'	System	29 Aug 2020 16:06:49
User entered '29 Aug 2020 12:06'	System	29 Aug 2020 16:06:49

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 6'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:32:49', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '56b67015-4a00-45c1-b0d5-24dfbb4b2339'	System	30 Aug 2020 19:33:07
User entered 'None (1)'	System	30 Aug 2020 19:33:07

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:32:54', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '56b67015-4a00-45c1-b0d5-24dfbb4b2339'	System	30 Aug 2020 19:33:07
User entered 'No (N)'	System	30 Aug 2020 19:33:07

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:32:57', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '56b67015-4a00-45c1-b0d5-24dfbb4b2339'	System	30 Aug 2020 19:33:07
User entered 'No (N)'	System	30 Aug 2020 19:33:07

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:03', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '56b67015-4a00-45c1-b0d5-24dfbb4b2339'	System	30 Aug 2020 19:33:07
User entered 'None (1)'	System	30 Aug 2020 19:33:07

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:06', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '56b67015-4a00-45c1-b0d5-24dfbb4b2339'	System	30 Aug 2020 19:33:07
User entered '30 Aug 2020 15:33'	System	30 Aug 2020 19:33:07

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 7'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:23', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '78e05109-a29c-409b-9d88-5a437838dc34'	System	31 Aug 2020 16:07:12
User entered 'None (1)'	System	31 Aug 2020 16:07:12

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:26', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '78e05109-a29c-409b-9d88-5a437838dc34'	System	31 Aug 2020 16:07:12
User entered 'No (N)'	System	31 Aug 2020 16:07:12

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:29', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '78e05109-a29c-409b-9d88-5a437838dc34'	System	31 Aug 2020 16:07:12
User entered 'No (N)'	System	31 Aug 2020 16:07:12

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:32', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '78e05109-a29c-409b-9d88-5a437838dc34'	System	31 Aug 2020 16:07:12
User entered 'None (1)'	System	31 Aug 2020 16:07:12

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:37', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '78e05109-a29c-409b-9d88-5a437838dc34'	System	31 Aug 2020 16:07:12
User entered '31 Aug 2020 12:03'	System	31 Aug 2020 16:07:12

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:47:57', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5fda991a-29c1-47bb-b3c6-f5b6ff5ac5f4'	System	25 Aug 2020 14:48:35
User entered 'None (0)'	System	25 Aug 2020 14:48:35

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:48:07', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5fda991a-29c1-47bb-b3c6-f5b6ff5ac5f4'	System	25 Aug 2020 14:48:35
User entered 'None (0)'	System	25 Aug 2020 14:48:35

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:48:12', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5fda991a-29c1-47bb-b3c6-f5b6ff5ac5f4'	System	25 Aug 2020 14:48:35
User entered 'None (0)'	System	25 Aug 2020 14:48:35

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:48:15', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5fda991a-29c1-47bb-b3c6-f5b6ff5ac5f4'	System	25 Aug 2020 14:48:35
User entered 'None (0)'	System	25 Aug 2020 14:48:35

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:48:18', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5fda991a-29c1-47bb-b3c6-f5b6ff5ac5f4'	System	25 Aug 2020 14:48:35
User entered 'None (0)'	System	25 Aug 2020 14:48:35

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:48:22', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5fda991a-29c1-47bb-b3c6-f5b6ff5ac5f4'	System	25 Aug 2020 14:48:35
User entered 'None (0)'	System	25 Aug 2020 14:48:35

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:48:29', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5fda991a-29c1-47bb-b3c6-f5b6ff5ac5f4'	System	25 Aug 2020 14:48:35
User entered 'No (N)'	System	25 Aug 2020 14:48:35

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T10:48:32', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '5fda991a-29c1-47bb-b3c6-f5b6ff5ac5f4'	System	25 Aug 2020 14:48:35
User entered '25 Aug 2020 10:48'	System	25 Aug 2020 14:48:35

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 10:34'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 13:04'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:37', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '24472d2a-27cb-4664-8b56-1d5c600ec4d9'	System	25 Aug 2020 20:53:05
User entered 'None (0)'	System	25 Aug 2020 20:53:05

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:39', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '24472d2a-27cb-4664-8b56-1d5c600ec4d9'	System	25 Aug 2020 20:53:05
User entered 'None (0)'	System	25 Aug 2020 20:53:05

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:43', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '24472d2a-27cb-4664-8b56-1d5c600ec4d9'	System	25 Aug 2020 20:53:05
User entered 'None (0)'	System	25 Aug 2020 20:53:05

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:46', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '24472d2a-27cb-4664-8b56-1d5c600ec4d9'	System	25 Aug 2020 20:53:05
User entered 'None (0)'	System	25 Aug 2020 20:53:05

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:51', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '24472d2a-27cb-4664-8b56-1d5c600ec4d9'	System	25 Aug 2020 20:53:05
User entered 'None (0)'	System	25 Aug 2020 20:53:05

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:54', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '24472d2a-27cb-4664-8b56-1d5c600ec4d9'	System	25 Aug 2020 20:53:05
User entered 'None (0)'	System	25 Aug 2020 20:53:05

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:52:58', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '24472d2a-27cb-4664-8b56-1d5c600ec4d9'	System	25 Aug 2020 20:53:05
User entered 'No (N)'	System	25 Aug 2020 20:53:05

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-25T16:53:01', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '24472d2a-27cb-4664-8b56-1d5c600ec4d9'	System	25 Aug 2020 20:53:05
User entered '25 Aug 2020 16:53'	System	25 Aug 2020 20:53:05

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 13:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 2'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:12:42', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '93479bb3-cd70-4b96-8eed-82581409ef9e'	System	26 Aug 2020 16:13:24
User entered 'None (0)'	System	26 Aug 2020 16:13:24

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:12:48', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '93479bb3-cd70-4b96-8eed-82581409ef9e'	System	26 Aug 2020 16:13:24
User entered 'No interference with activity (1)'	System	26 Aug 2020 16:13:24

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:12:56', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '93479bb3-cd70-4b96-8eed-82581409ef9e'	System	26 Aug 2020 16:13:24
User entered 'None (0)'	System	26 Aug 2020 16:13:24

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:13:03', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '93479bb3-cd70-4b96-8eed-82581409ef9e'	System	26 Aug 2020 16:13:24
User entered 'None (0)'	System	26 Aug 2020 16:13:24

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:13:07', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '93479bb3-cd70-4b96-8eed-82581409ef9e'	System	26 Aug 2020 16:13:24
User entered 'None (0)'	System	26 Aug 2020 16:13:24

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:13:10', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '93479bb3-cd70-4b96-8eed-82581409ef9e'	System	26 Aug 2020 16:13:24
User entered 'None (0)'	System	26 Aug 2020 16:13:24

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:13:17', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '93479bb3-cd70-4b96-8eed-82581409ef9e'	System	26 Aug 2020 16:13:24
User entered 'No (N)'	System	26 Aug 2020 16:13:24

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-26T12:13:21', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '93479bb3-cd70-4b96-8eed-82581409ef9e'	System	26 Aug 2020 16:13:24
User entered '26 Aug 2020 12:13'	System	26 Aug 2020 16:13:24

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 3'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:26:29', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2703b15c-e283-4589-a2f6-d6e7cb2222c3'	System	27 Aug 2020 16:27:08
User entered 'None (0)'	System	27 Aug 2020 16:27:08

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:26:33', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2703b15c-e283-4589-a2f6-d6e7cb2222c3'	System	27 Aug 2020 16:27:08
User entered 'No interference with activity (1)'	System	27 Aug 2020 16:27:08

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:26:37', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2703b15c-e283-4589-a2f6-d6e7cb2222c3'	System	27 Aug 2020 16:27:08
User entered 'None (0)'	System	27 Aug 2020 16:27:08

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:26:45', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2703b15c-e283-4589-a2f6-d6e7cb2222c3'	System	27 Aug 2020 16:27:08
User entered 'None (0)'	System	27 Aug 2020 16:27:08

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:26:52', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2703b15c-e283-4589-a2f6-d6e7cb2222c3'	System	27 Aug 2020 16:27:08
User entered 'None (0)'	System	27 Aug 2020 16:27:08

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:26:55', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2703b15c-e283-4589-a2f6-d6e7cb2222c3'	System	27 Aug 2020 16:27:08
User entered 'None (0)'	System	27 Aug 2020 16:27:08

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:27:00', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2703b15c-e283-4589-a2f6-d6e7cb2222c3'	System	27 Aug 2020 16:27:08
User entered 'No (N)'	System	27 Aug 2020 16:27:08

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-27T12:27:03', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '2703b15c-e283-4589-a2f6-d6e7cb2222c3'	System	27 Aug 2020 16:27:08
User entered '27 Aug 2020 12:27'	System	27 Aug 2020 16:27:08

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 4'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:20:02', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '88327cfc-b43e-4d60-8f86-6ab86d95ff3f'	System	28 Aug 2020 19:20:31
User entered 'None (0)'	System	28 Aug 2020 19:20:31

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:20:07', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '88327cfc-b43e-4d60-8f86-6ab86d95ff3f' User entered 'None (0)'	System	28 Aug 2020 19:20:31
	System	28 Aug 2020 19:20:31

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:20:11', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '88327cfc-b43e-4d60-8f86-6ab86d95ff3f'	System	28 Aug 2020 19:20:31
User entered 'None (0)'	System	28 Aug 2020 19:20:31

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:20:14', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '88327cfc-b43e-4d60-8f86-6ab86d95ff3f'	System	28 Aug 2020 19:20:31
User entered 'None (0)'	System	28 Aug 2020 19:20:31

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:20:18', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '88327cfc-b43e-4d60-8f86-6ab86d95ff3f'	System	28 Aug 2020 19:20:31
User entered 'None (0)'	System	28 Aug 2020 19:20:31

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:20:22', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '88327cfc-b43e-4d60-8f86-6ab86d95ff3f'	System	28 Aug 2020 19:20:31
User entered 'None (0)'	System	28 Aug 2020 19:20:31

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:20:26', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '88327cfc-b43e-4d60-8f86-6ab86d95ff3f'	System	28 Aug 2020 19:20:31
User entered 'No (N)'	System	28 Aug 2020 19:20:31

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-28T15:20:29', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '88327cfc-b43e-4d60-8f86-6ab86d95ff3f' User entered '28 Aug 2020 15:20'	System	28 Aug 2020 19:20:31

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 5'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:52', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '25ae789b-3175-416a-a031-f40934e8c1f5'	System	29 Aug 2020 16:07:23
User entered 'None (0)'	System	29 Aug 2020 16:07:23

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:06:56', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '25ae789b-3175-416a-a031-f40934e8c1f5'	System	29 Aug 2020 16:07:23
User entered 'None (0)'	System	29 Aug 2020 16:07:23

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:07:01', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '25ae789b-3175-416a-a031-f40934e8c1f5'	System	29 Aug 2020 16:07:23
User entered 'None (0)'	System	29 Aug 2020 16:07:23

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:07:05', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '25ae789b-3175-416a-a031-f40934e8c1f5'	System	29 Aug 2020 16:07:23
User entered 'None (0)'	System	29 Aug 2020 16:07:23

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:07:08', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '25ae789b-3175-416a-a031-f40934e8c1f5'	System	29 Aug 2020 16:07:23
User entered 'None (0)'	System	29 Aug 2020 16:07:23

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:07:14', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '25ae789b-3175-416a-a031-f40934e8c1f5'	System	29 Aug 2020 16:07:23
User entered 'None (0)'	System	29 Aug 2020 16:07:23

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:07:18', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '25ae789b-3175-416a-a031-f40934e8c1f5'	System	29 Aug 2020 16:07:23
User entered 'No (N)'	System	29 Aug 2020 16:07:23

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-29T12:07:21', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '25ae789b-3175-416a-a031-f40934e8c1f5'	System	29 Aug 2020 16:07:23
User entered '29 Aug 2020 12:07'	System	29 Aug 2020 16:07:23

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 6'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:13', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ae7f7480-20fd-4f71-b47c-7c43323c7772'	System	30 Aug 2020 19:33:43
User entered 'None (0)'	System	30 Aug 2020 19:33:43

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:16', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ae7f7480-20fd-4f71-b47c-7c43323c7772'	System	30 Aug 2020 19:33:43
User entered 'None (0)'	System	30 Aug 2020 19:33:43

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:20', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ae7f7480-20fd-4f71-b47c-7c43323c7772'	System	30 Aug 2020 19:33:43
User entered 'None (0)'	System	30 Aug 2020 19:33:43

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:26', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ae7f7480-20fd-4f71-b47c-7c43323c7772'	System	30 Aug 2020 19:33:43
User entered 'None (0)'	System	30 Aug 2020 19:33:43

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:31', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ae7f7480-20fd-4f71-b47c-7c43323c7772'	System	30 Aug 2020 19:33:43
User entered 'None (0)'	System	30 Aug 2020 19:33:43

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:35', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ae7f7480-20fd-4f71-b47c-7c43323c7772'	System	30 Aug 2020 19:33:43
User entered 'None (0)'	System	30 Aug 2020 19:33:43

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:39', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ae7f7480-20fd-4f71-b47c-7c43323c7772'	System	30 Aug 2020 19:33:43
User entered 'No (N)'	System	30 Aug 2020 19:33:43

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-30T15:33:42', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ae7f7480-20fd-4f71-b47c-7c43323c7772'	System	30 Aug 2020 19:33:43
User entered '30 Aug 2020 15:33'	System	30 Aug 2020 19:33:43

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Aug 2020 14:21:30
User entered 'Day 7'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:46', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f8418344-2e3f-4cd1-a01c-f186f37c302e'	System	31 Aug 2020 16:07:58
User entered 'None (0)'	System	31 Aug 2020 16:07:58

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:48', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f8418344-2e3f-4cd1-a01c-f186f37c302e'	System	31 Aug 2020 16:07:58
User entered 'None (0)'	System	31 Aug 2020 16:07:58

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:52', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f8418344-2e3f-4cd1-a01c-f186f37c302e'	System	31 Aug 2020 16:07:58
User entered 'None (0)'	System	31 Aug 2020 16:07:58

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:54', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f8418344-2e3f-4cd1-a01c-f186f37c302e'	System	31 Aug 2020 16:07:58
User entered 'None (0)'	System	31 Aug 2020 16:07:58

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:57', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f8418344-2e3f-4cd1-a01c-f186f37c302e'	System	31 Aug 2020 16:07:58
User entered 'None (0)'	System	31 Aug 2020 16:07:58

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:03:59', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f8418344-2e3f-4cd1-a01c-f186f37c302e'	System	31 Aug 2020 16:07:58
User entered 'None (0)'	System	31 Aug 2020 16:07:58

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:04:03', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f8418344-2e3f-4cd1-a01c-f186f37c302e'	System	31 Aug 2020 16:07:58
User entered 'No (N)'	System	31 Aug 2020 16:07:58

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-08-31T12:04:07', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'f8418344-2e3f-4cd1-a01c-f186f37c302e'	System	31 Aug 2020 16:07:58
User entered '31 Aug 2020 12:04'	System	31 Aug 2020 16:07:58

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 14:21:30

US3402042

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 14:21:30

US3402042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	02 Sep 2020 11:19:06

US3402042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:10:39
User entered '1 Sep 2020'	Traci Hull (b) (4)	02 Sep 2020 11:19:06

US3402042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[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)	02 Sep 2020 11:19:06

US3402042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	02 Sep 2020 11:19:06

US3402042

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	02 Sep 2020 11:19:13

US3402042

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 11:19:13

US3402042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	15 Sep 2020 14:17:27

US3402042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Traci Hull (b) (4) (b) (4)	15 Sep 2020 14:17:27

US3402042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[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)	15 Sep 2020 14:17:27

US3402042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	15 Sep 2020 14:17:27

US3402042

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	15 Sep 2020 14:17:35

US3402042

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 14:17:35

US3402042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	15 Sep 2020 14:17:49

US3402042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Traci Hull (b) (4) (b) (4)	15 Sep 2020 14:17:49

US3402042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[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)	15 Sep 2020 14:17:49

US3402042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	15 Sep 2020 14:17:49

US3402042

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	15 Sep 2020 14:17:52

US3402042

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 14:17:52

US3402042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 15:11:54

US3402042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 15:11:54

US3402042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

[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)	24 Sep 2020 15:11:54

US3402042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	24 Sep 2020 15:11:54

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '09:05'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '24 Sep 2020 09:05'	System	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Traci Hull (b) (4) (b) (4)	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '72'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '22'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '130'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '78'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Sep 2020 15:12:56

US3402042

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 15:13:06

US3402042

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Sep 2020 15:13:06

US3402042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 15:13:20

US3402042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 15:13:20

US3402042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '09:12'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 15:13:20

US3402042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '24 Sep 2020 09:12'	System	24 Sep 2020 15:13:20

US3402042

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Sep 2020 15:13:24

US3402042

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 15:13:24

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 64'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-09-27T10:49:33', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b85d03a5-02bf-4703-a88e-3ae5c2e0390c'	System	27 Sep 2020 14:49:52
User entered 'No (N)'	System	27 Sep 2020 14:49:52

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

Have you been exposed to someone with 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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-09-27T10:49:40', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b85d03a5-02bf-4703-a88e-3ae5c2e0390c'	System	27 Sep 2020 14:49:52
User entered 'No (N)'	System	27 Sep 2020 14:49:52

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-09-27T10:49:50', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'b85d03a5-02bf-4703-a88e-3ae5c2e0390c' User entered '27 Sep 2020 10:49:50'	System	27 Sep 2020 14:49:52
	System	27 Sep 2020 14:49:52

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '27 Sep 2020 00:01'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '01 Oct 2020 23:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 71'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-04T08:51:50', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0db44fef-3938-49d5-ba8e-591cc6857238'	System	04 Oct 2020 15:28:05
User entered 'Yes (Y)'	System	04 Oct 2020 15:28:05

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

Have you been exposed to someone with 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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-04T08:52:01', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0db44fef-3938-49d5-ba8e-591cc6857238'	System	04 Oct 2020 15:28:05
User entered 'No (N)'	System	04 Oct 2020 15:28:05

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-04T08:52:11', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0db44fef-3938-49d5-ba8e-591cc6857238'	System	04 Oct 2020 15:28:05
User entered 'No (N)'	System	04 Oct 2020 15:28:05

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-04T08:52:17', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0db44fef-3938-49d5-ba8e-591cc6857238'	System	04 Oct 2020 15:28:05
User entered 'Yes (Y)'	System	04 Oct 2020 15:28:05

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Please 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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-04T11:27:35', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0db44fef-3938-49d5-ba8e-591cc6857238'	System	04 Oct 2020 15:28:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Oct 2020 15:28:05

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-04T11:27:56', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0db44fef-3938-49d5-ba8e-591cc6857238' User entered '04 Oct 2020 11:27:56'	System	04 Oct 2020 15:28:05
	System	04 Oct 2020 15:28:05

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '04 Oct 2020 00:01'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '08 Oct 2020 23:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 78'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-12T16:38:31', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '749aec17-2e68-4344-9ce8-2bb164260d24'	System	12 Oct 2020 20:39:23
User entered 'Yes (Y)'	System	12 Oct 2020 20:39:23

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

Have you been exposed to someone with 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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-12T16:38:38', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '749aec17-2e68-4344-9ce8-2bb164260d24'	System	12 Oct 2020 20:39:23
User entered 'No (N)'	System	12 Oct 2020 20:39:23

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-12T16:38:46', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '749aec17-2e68-4344-9ce8-2bb164260d24'	System	12 Oct 2020 20:39:23
User entered 'No (N)'	System	12 Oct 2020 20:39:23

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-12T16:38:57', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '749aec17-2e68-4344-9ce8-2bb164260d24'	System	12 Oct 2020 20:39:23
User entered 'Yes (Y)'	System	12 Oct 2020 20:39:23

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Please 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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-12T16:39:08', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '749aec17-2e68-4344-9ce8-2bb164260d24'	System	12 Oct 2020 20:39:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Oct 2020 20:39:23

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-12T16:39:12', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '749aec17-2e68-4344-9ce8-2bb164260d24'	System	12 Oct 2020 20:39:23
User entered '12 Oct 2020 16:39:12'	System	12 Oct 2020 20:39:23

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '11 Oct 2020 00:01'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '15 Oct 2020 23:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 92'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-25T22:22:41', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6ea8106a-3883-44fb-b89c-76fa232cd56c'	System	26 Oct 2020 02:23:13
User entered 'Yes (Y)'	System	26 Oct 2020 02:23:13

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

Have you been exposed to someone with 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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-25T22:22:48', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6ea8106a-3883-44fb-b89c-76fa232cd56c'	System	26 Oct 2020 02:23:13
User entered 'No (N)'	System	26 Oct 2020 02:23:13

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-25T22:22:54', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6ea8106a-3883-44fb-b89c-76fa232cd56c'	System	26 Oct 2020 02:23:13
User entered 'No (N)'	System	26 Oct 2020 02:23:13

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-25T22:23:02', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6ea8106a-3883-44fb-b89c-76fa232cd56c'	System	26 Oct 2020 02:23:13
User entered 'No (N)'	System	26 Oct 2020 02:23:13

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-10-25T22:23:08', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '6ea8106a-3883-44fb-b89c-76fa232cd56c'	System	26 Oct 2020 02:23:13
User entered '25 Oct 2020 22:23:08'	System	26 Oct 2020 02:23:13

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '25 Oct 2020 00:01'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '29 Oct 2020 23:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 99'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-01T19:05:09', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ed582560-ad5a-4102-badd-d5a3bc1bf23f'	System	02 Nov 2020 00:05:24
User entered 'No (N)'	System	02 Nov 2020 00:05:24

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

Have you been exposed to someone with 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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-01T19:05:15', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ed582560-ad5a-4102-badd-d5a3bc1bf23f'	System	02 Nov 2020 00:05:24
User entered 'No (N)'	System	02 Nov 2020 00:05:24

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-01T19:05:22', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: 'ed582560-ad5a-4102-badd-d5a3bc1bf23f'	System	02 Nov 2020 00:05:24
User entered '01 Nov 2020 19:05:22'	System	02 Nov 2020 00:05:24

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '01 Nov 2020 00:01'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '05 Nov 2020 23:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 106'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-08T22:07:27', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0312886b-4ec9-4aad-ba14-e2d418bffb6f' User entered 'No (N)'	System	09 Nov 2020 03:07:44

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

Have you been exposed to someone with 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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-08T22:07:35', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0312886b-4ec9-4aad-ba14-e2d418bffb6f'	System	09 Nov 2020 03:07:44
User entered 'No (N)'	System	09 Nov 2020 03:07:44

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-08T22:07:41', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0312886b-4ec9-4aad-ba14-e2d418bffb6f' User entered '08 Nov 2020 22:07:41'	System	09 Nov 2020 03:07:44
	System	09 Nov 2020 03:07:44

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '08 Nov 2020 00:01'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '12 Nov 2020 23:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered 'Day 113'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-15T22:38:38', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0ba7a10a-4b74-4087-84b3-d0098186d870'	System	16 Nov 2020 03:38:53
User entered 'No (N)'	System	16 Nov 2020 03:38:53

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

Have you been exposed to someone with 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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-15T22:38:47', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0ba7a10a-4b74-4087-84b3-d0098186d870'	System	16 Nov 2020 03:38:53
User entered 'No (N)'	System	16 Nov 2020 03:38:53

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-15T22:38:51', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '0ba7a10a-4b74-4087-84b3-d0098186d870'	System	16 Nov 2020 03:38:53
User entered '15 Nov 2020 22:38:51'	System	16 Nov 2020 03:38:53

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '15 Nov 2020 00:01'	System	28 Jul 2020 15:07:15

US3402042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Jul 2020 15:07:15
User entered '19 Nov 2020 23:59'	System	28 Jul 2020 15:07:15

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '24 Sep 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '28 Sep 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '01 Oct 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '05 Oct 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '08 Oct 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '12 Oct 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '15 Oct 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '19 Oct 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '22 Oct 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '26 Oct 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '29 Oct 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '02 Nov 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '05 Nov 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '09 Nov 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '12 Nov 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '16 Nov 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-20T10:08:46', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3548a66b-1e35-4a55-ab9f-6d29796ab6a0' User entered 'No (N)'	System	20 Nov 2020 15:08:58
	System	20 Nov 2020 15:08:58

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

Have you been exposed to someone with 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 (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-20T10:08:51', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3548a66b-1e35-4a55-ab9f-6d29796ab6a0' User entered 'No (N)'	System	20 Nov 2020 15:08:58

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0BADAA9F-AFD9-4F1C-B27F-5C998617A734)', Time: '2020-11-20T10:08:55', User OID: 'PatientReportedOutcome (US3402042)', ODM File OID: '3548a66b-1e35-4a55-ab9f-6d29796ab6a0' User entered '20 Nov 2020 10:08:55'	System	20 Nov 2020 15:08:58
	System	20 Nov 2020 15:08:58

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 02:22:03

US3402042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:22:03
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 02:22:03

US3402042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:35:49

US3402042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:35:49

US3402042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[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)	19 Oct 2020 21:35:49

US3402042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:35:49

US3402042

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:35:38

US3402042

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 21:35:38

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:19

[Date of Contact](#)

Audit	User	Time (GMT)
User closed query 'Please review CCG V2.0 and use the "Add Event" function to add the illness folder. ' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 19:59:38
Query 'Please review CCG V2.0 and use the "Add Event" function to add the illness folder. ' answered with 'Updated' (Site from CRA).	Jennifer Molstead (b) (4)	30 Oct 2020 13:18:01
User opened query 'Please review CCG V2.0 and use the "Add Event" function to add the illness folder. ' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 00:59:53
User closed query 'Subject has covid assessment done but no Illness or Convalescent visit. Please confirm if there was an illness visit and convalescent follow up done. ' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 00:59:53
Query 'Subject has covid assessment done but no Illness or Convalescent visit. Please confirm if there was an illness visit and convalescent follow up done. ' answered with 'ILLNESS VISIT WAS DONE-NO ILLNESS VISIT PAGE IS GENERATING' (Site from CRA).	Abigail Wine (b) (4)	29 Oct 2020 22:55:06
User opened query 'Subject has covid assessment done but no Illness or Convalescent visit. Please confirm if there was an illness visit and convalescent follow up done. ' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:01:35
User entered '12 Oct 2020'	Traci Hull (b) (4)	13 Oct 2020 13:07:30

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:19

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '14:00'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:07:30

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:19

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 14:00'	System	13 Oct 2020 13:07:30

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:19

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:07:30

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:19

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:07:30

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[Date](#)

Audit	User	Time (GMT)
Query 'Per CDM: Please confirm initial start date of symptoms and Contact date are the same (12OCT2020) or update accordingly' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4)	09 Nov 2020 23:10:22
User entered '01 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	09 Nov 2020 23:10:11
User opened query 'Per CDM: Please confirm initial start date of symptoms and Contact date are the same (12OCT2020) or update accordingly' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:58:06
User entered '12 Oct 2020'	Traci Hull (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '93'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[Temperature](#)

Audit	User	Time (GMT)
User entered '96.3' F	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[Cough](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:19

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:08:37

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[Date](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '90'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.3' F	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:19

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 14:40:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[Date](#)

Audit	User	Time (GMT)
User closed query 'Subject hasn't entered symptom log for 13Oct20 - 16Oct20, and days following 16Oct20. Subject still appears to have mild cough, nasal congestion, and runny nose reported as of 16Oct20' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 01:01:07
Query 'Subject hasn't entered symptom log for 13Oct20 - 16Oct20, and days following 16Oct20. Subject still appears to have mild cough, nasal congestion, and runny nose reported as of 16Oct20' answered with 'Subject swab result were negative. Subject was taken out of illness phase' (Site from CRA).	Jennifer Molstead (b) (4)	29 Oct 2020 22:30:08
User opened query 'Subject hasn't entered symptom log for 13Oct20 - 16Oct20, and days following 16Oct20. Subject still appears to have mild cough, nasal congestion, and runny nose reported as of 16Oct20' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 16:04:01
User entered '16 Oct 2020'	Traci Hull (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '90'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.7' F	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:19

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:57:24

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:19

[Date of Visit](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Jennifer Molstead (b) (4) (b) (4)	15 Oct 2020 12:19:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:19

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	15 Oct 2020 12:19:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:19

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	15 Oct 2020 12:19:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:19

[Date of Test](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Jennifer Molstead (b) (4) (b) (4)	15 Oct 2020 12:19:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:19

[Type of Test Performed](#)

Audit	User	Time (GMT)
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jennifer Molstead (b) (4)	15 Oct 2020 12:19:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:19

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	15 Oct 2020 12:19:56
	(b) (4)	

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:19

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	15 Oct 2020 12:19:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:19

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	15 Oct 2020 12:19:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:19

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	15 Oct 2020 12:19:56

US3402042

Folder: Covid-19 Assessment 12 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:19

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Oct 2020 12:19:56

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:23:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:23:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:23:19

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:23:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:23:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:23:19

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:23:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:23:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:23:19

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:23:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:23:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:23:19

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:23:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:23:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:23:19

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:23:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:23:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:23:19

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:23:19

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:23:19

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:23:19

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	30 Oct 2020 10:51:09
	(b) (4)	

US3402042

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:48:17
	(b) (4)	

US3402042

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:48:17

US3402042

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:48:17
	(b) (4)	

US3402042

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	30 Oct 2020 10:48:17

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:49:11

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:49:11

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '14:19'	Jennifer Molstead (b) (4)	30 Oct 2020 10:49:11
	(b) (4)	

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '12 Oct 2020 14:19'	System	30 Oct 2020 10:49:11

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

Height (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	30 Oct 2020 10:49:11
DataPoint set to visible.	(b) (4) System	30 Oct 2020 10:48:17

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

Weight (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	30 Oct 2020 10:49:11
DataPoint set to visible.	(b) (4) System	30 Oct 2020 10:48:17

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

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).	(b) (4), (b) (6)	03 Nov 2020 11:15:07
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.'	Jennifer Molstead (b) (4)	30 Oct 2020 10:49:32
answered with 'NCS' (Site from System).	(b) (4)	
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	30 Oct 2020 10:49:11
User entered '96.3' F	Jennifer Molstead (b) (4)	30 Oct 2020 10:49:11
	(b) (4)	

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:49:11
	(b) (4)	

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	30 Oct 2020 10:49:11
	(b) (4)	

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '73'	Jennifer Molstead (b) (4)	30 Oct 2020 10:49:11
	(b) (4)	

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Oct 2020 10:49:11

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '18'	Jennifer Molstead (b) (4)	30 Oct 2020 10:49:11
	(b) (4)	

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Oct 2020 10:49:11

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per previous responses, Systolic and Diastolic Blood Pressure results were Clinically Significant however there is no corresponding Adverse Event recorded. Please review and reconcile data or explain.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 13:51:42
Query 'Per CDM: Per previous responses, Systolic and Diastolic Blood Pressure results were Clinically Significant however there is no corresponding Adverse Event recorded. Please review and reconcile data or explain.' answered with 'CORRECT AS IS. SUBJECT SENT TO EMERGENCY ROOM.' (Site from DM).	Traci Hull (b) (4) (b) (4)	03 Nov 2020 15:46:10
User entered '150' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	03 Nov 2020 15:43:07
User opened query 'Per CDM: Per previous responses, Systolic and Diastolic Blood Pressure results were Clinically Significant however there is no corresponding Adverse Event recorded. Please review and reconcile data or explain.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:18:46
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 11:15:14
Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Subject was advised to go to the emergency room CS' (Site from System).	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:50:03
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	30 Oct 2020 10:49:11
User entered '74'	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:49:11

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Oct 2020 10:49:11

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

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)	05 Nov 2020 13:51:45
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 'CORRECT AS IS. SUBJECT WAS SENT TO EMERGENCY ROOM.' (Site from System).	Traci Hull (b) (4) (b) (4)	03 Nov 2020 15:46:28
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		03 Nov 2020 15:43:07
User entered '58' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	03 Nov 2020 15:43:07
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)	03 Nov 2020 11:15:15
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 'Subject was advised to go to the emergency room CS' (Site from System).	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:50:05
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		30 Oct 2020 10:49:11
User entered '54'	Jennifer Molstead (b) (4) (b) (4)	30 Oct 2020 10:49:11

US3402042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Oct 2020 10:49:11

US3402042

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:50:28
	(b) (4)	

US3402042

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	30 Oct 2020 10:50:28
	(b) (4)	

US3402042

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:23:19

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	30 Oct 2020 10:50:40
	(b) (4)	

US3402042

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:23:19

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	30 Oct 2020 10:50:40
	(b) (4)	

US3402042

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:23:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:38
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4)	07 Oct 2020 13:31:04
User entered 'No (N)'	Traci Hull (b) (4)	03 Sep 2020 14:38:32

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 22:10:34
Un-reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 22:10:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:43:09
User entered 'USA-US059-2020-mRNA-1273-P301000006'	System	14 Oct 2020 13:43:03
User entered 'New'	(b) (4), (b) (6)	14 Oct 2020 13:43:03

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Emphysema - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 15:21:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 15:21:45
Data point term sent to Coder	System	07 Oct 2020 13:33:53
User entered 'WORSENING OF EMPHYSEMA'	Traci Hull (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:48:58
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 12:12:45
	(b) (4)	
User entered '01 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:12:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered '1 Oct 2020'	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered empty.	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	29 Oct 2020 22:40:26
User entered 'Yes (Y)'	Traci Hull (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 15:12:37
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	29 Oct 2020 22:41:41
User entered '17 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	29 Oct 2020 22:40:26
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:32:02
User entered empty.	Traci Hull (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered empty.	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	13 Oct 2020 22:01:40
User entered 'No (N)'	Traci Hull (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered '0'	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered '0'	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 08:29:32
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject is still inpatient.' (Site from System).	Jennifer Molstead (b) (4)	13 Oct 2020 22:02:12
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	13 Oct 2020 22:01:40
User entered '1' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	13 Oct 2020 22:01:40
User entered '0'	Traci Hull (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered '13 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	13 Oct 2020 22:01:40
User entered empty.	Traci Hull (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 15:12:43
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	29 Oct 2020 22:41:47
User entered '17 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	29 Oct 2020 22:40:26
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:32:42
User entered empty.	Traci Hull (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'No (N)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	13 Oct 2020 22:02:16
User entered empty.	Traci Hull (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered empty.	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered '0'	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered '0'	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered '0'	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'Not Related (NOT RELATED)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'Not Related (NOT RELATED)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered 'Not Applicable (NOT APPLICABLE)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered '0'	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered '1'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered '0'	Traci Hull (b) (4)	07 Oct 2020 13:33:02
	(b) (4)	

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 15:12:50
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	29 Oct 2020 22:41:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	29 Oct 2020 22:40:26
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:33:29
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Traci Hull (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User entered empty.	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:14:26
User closed query 'Per DM CLR: SAE Narrative indicates Oxygen and Azithromycin were given. However, there is no corresponding ConMed record that match these medication. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 11:16:21
User closed query 'PV Query: Please report if there was any trigger for the worsening of emphysema (ie. infection, medication noncompliance, etc.).' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 15:13:07
User closed query 'PV Query: It was noted that the subject was treated with azithromycin. Please update the treatment medications to reflect the details (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 15:13:03
User closed query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 15:11:49
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 15:11:39
Query 'Per DM CLR: SAE Narrative indicates Oxygen and Azithromycin were given. However, there is no corresponding ConMed record that match these medication. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4)	29 Oct 2020 22:49:52
Query 'PV Query: Please report if there was any trigger for the worsening of emphysema (ie. infection, medication noncompliance, etc.).' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	29 Oct 2020 22:49:44
Query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'None provided' (Site from Safety).	Jennifer Molstead (b) (4)	29 Oct 2020 22:49:39

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject began with congestion 01OCT2020 Went to his pulmonologist and was started on prednisone and Cefdir. SUBJECT CAME FOR ILLNESS VISIT 12OCT2020. AFTER HAVING PHYSICAL EXAM IT WAS DETERMINED BY SUB INVESTIGATOR THAT SUBJECT SHOULD GO THE THE EMERGENCY ROOM FOR FURTHER EVALUATION. SUBJECT WAS LATER ADMITTED TO HOSPITAL FOR FURTHER TREATMENT. SUBJCT HAD CHEST XRAY WHICH SHOWED CHANGES IN BTH LUNGS PARTICULARLY WITH IN THE UPPER LOBES WITH LINEAR SCARRING WITH IN THE MID AND LOWER LUNG ZONES AS NOTED ON PREIOUS STUDIES. SUBJECT IS ON 3L OF OXYGEN BY NASAL CANNULA. SUBJECT WILL CONTINUE ON CEFTRIAXONE, AND AZITHROMYCIN,. WILL BE STARTED ON METHYLPREDNISOLONE.' reason for change: New Information	Jennifer Molstead (b) (4)	29 Oct 2020 22:49:05
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'no covid test preformed' (Site from Safety).	Jennifer Molstead (b) (4)	29 Oct 2020 22:44:04
Query 'PV Query: It was noted that the subject was treated with azithromycin. Please update the treatment medications to reflect the details (including dates of administration, dose, units, frequency, route and indication).' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	29 Oct 2020 22:42:41
User opened query 'Per DM CLR: SAE Narrative indicates Oxygen and Azithromycin were given. However, there is no corresponding ConMed record that match these medication. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:00:21
User opened query 'PV Query: Please report if there was any trigger for the worsening of emphysema (ie. infection, medication noncompliance, etc.).' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:35:26

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:34:25
User opened query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:34:05
User opened query 'PV Query: It was noted that the subject was treated with azithromycin. Please update the treatment medications to reflect the details (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:33:47
User entered 'SUBJECT CAME FOR ILLNESS VISIT 12OCT2020. AFTER HAVING PHYSICAL EXAM IT WAS DETERMINED BY SUB INVESTIGATOR THAT SUBJECT SHOULD GO THE THE EMERGENCY ROOM FOR FURTHER EVALUATION. SUBJECT WAS LATER ADMITTED TO HOSPITAL FOR FURTHER TREATMENT. SUBJCT HAD CHEST XRAY WHICH SHOWED CHANGES IN BTH LUNGS PARTICULARLY WITH IN THE UPPER LOBES WITH LINEAR SCARRING WITH IN THE MID AND LOWER LUNG ZONES AS NOTED ON PREIOUS STUDIES. SUBJECT IS ON 3L OF OXYGEN BY NASAL CANNULA. SUBJECT WILL CONTINUE ON CEFTRIAXONE, AND AZITHROMYCIN,. WILL BE STARTED ON METHYLPREDNISOLONE.' reason for change: New Information	Jennifer Molstead (b) (4)	18 Oct 2020 14:20:53
User entered 'Subject came for Illness visit 12Oct2020. After having physical exam it was determined by Sub investigator that subject should go the the emergency room for further evaluation. Subject was later admitted to hospital for further treatment.' reason for change: New Information	Jennifer Molstead (b) (4)	13 Oct 2020 22:01:40
User entered empty.	Traci Hull (b) (4)	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 22:01:40
User entered '0'	System	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 13:33:02

US3402042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 22:02:16

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:23:19

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:20:56
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	26 Sep 2020 13:58:15
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
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)	26 Sep 2020 14:01:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 14:01:45
Data point term sent to Coder	System	26 Sep 2020 14:00:37
User entered 'ELIQUIS'	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'DEEP VEIN THROMBOSIS/ PULMINARY EMBOLISM'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 13:59:40

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '5'	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'UN UNK 2018'	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 13:59:40

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 13:59:40

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 13:59:40

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 13:59:40

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
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)	27 Sep 2020 10:35:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	27 Sep 2020 10:35:44
Data point term sent to Coder	System	26 Sep 2020 14:01:37
User entered 'TOMSULOSIN'	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'BENIGN PROSTATIC HYPERTROPHY'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:01:04

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User closed query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 10:20:11
Query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'CORRECT AS IS.' (Site from DM).	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:00:39
User entered '.04' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:00:29
User opened query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:45:47
User entered '.04'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:01:04

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'UN UNK 1992'	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:01:04
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:01:04

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:01:04

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 14:01:04

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 14:04:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 14:04:46
Data point term sent to Coder	System	26 Sep 2020 14:03:38
User entered 'FLUOXETINE'	Jennifer Molstead (b) (4)	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:02:39
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'DEPRESSION'	Jennifer Molstead (b) (4)	26 Sep 2020 14:02:39
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '40'	Jennifer Molstead (b) (4)	26 Sep 2020 14:02:39
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:02:39
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:02:39
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:02:39
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:02:39
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:02:39
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'UN UNK 2012'	Jennifer Molstead (b) (4)	26 Sep 2020 14:02:39
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	26 Sep 2020 14:02:39
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:02:39
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 14:02:39

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: BISOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 14:05:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 14:05:47
Data point term sent to Coder	System	26 Sep 2020 14:04:40
User entered 'BISOPROLOL'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'HYPERTENSION'	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '5'	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'UN UNK 2000'	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Jennifer Molstead (b) (4)	10 Nov 2020 15:31:20
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Jennifer Molstead (b) (4)	10 Nov 2020 15:31:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Jennifer Molstead (b) (4)	10 Nov 2020 15:31:20
User entered '17 Oct 2020' reason for change: New Information	Jennifer Molstead (b) (4)	10 Nov 2020 15:31:20
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:03:59
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 14:03:59

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 14:06:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 14:06:47
Data point term sent to Coder	System	26 Sep 2020 14:05:40
User entered 'HYDROCHLORATHIAZIDE'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:05:05
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'HYPERTENSION'	Jennifer Molstead (b) (4)	26 Sep 2020 14:05:05
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '6.25'	Jennifer Molstead (b) (4)	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:05:05
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:05:05
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:05:05
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:05:05
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:05:05
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'UN UNK 2000'	Jennifer Molstead (b) (4)	26 Sep 2020 14:05:05
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	26 Sep 2020 14:05:05
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:05:05
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:05:05
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 14:05:05

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 14:07:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 14:07:47
Data point term sent to Coder	System	26 Sep 2020 14:06:41
User entered 'OMEPRAZOLE'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:06:25
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 10:21:24
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'MED HISTORY UPDATED TO REFLECT GASTROESOPHAGEAL REFLUX DISEASE' (Site from DM).	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:03:02
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:48:31
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '40'	Jennifer Molstead (b) (4)	26 Sep 2020 14:06:25
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:06:25
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:06:25
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:06:25
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:06:25
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:06:25
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'UN UNK 1990'	Jennifer Molstead (b) (4)	26 Sep 2020 14:06:25
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	26 Sep 2020 14:06:25
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:06:25
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:06:25
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:06:25
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 14:06:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, PRODUCT: ROFLUMILAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 10:57:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 10:57:40
Data point term sent to Coder	System	26 Sep 2020 14:08:41
User entered 'ROFLUMILAST'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'EMPHYSEMA'	Jennifer Molstead (b) (4)	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User closed query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 10:21:33
Query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:07:48
User entered '250' reason for change: New Information	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:07:33
User opened query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:48:48
User entered '40'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'ug (ug)' reason for change: New Information	Traci Hull (b) (4)	05 Oct 2020 16:07:33
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:07:49
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:07:49
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:07:49
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:07:49
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:07:49
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'UN UNK 2016'	Jennifer Molstead (b) (4)	26 Sep 2020 14:07:49
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	26 Sep 2020 14:07:49
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:07:49
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 14:07:49

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FORMOTEROL FUMARATE;GLYCOPYRRONIUM BROMIDE, PRODUCTSYNONYM: BEVESPI AEROSPHERE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 14:11:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 14:11:47
Data point term sent to Coder	System	26 Sep 2020 14:10:42
User entered 'BEVESPI AEROSPHERE'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:10:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:10:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'EMPHYSEMA'	Jennifer Molstead (b) (4)	26 Sep 2020 14:10:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '9/4.8'	Jennifer Molstead (b) (4)	26 Sep 2020 14:10:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'ug (ug)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:10:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:10:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'twice daily (BID)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:10:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:10:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Jennifer Molstead (b) (4) (b) (4)	26 Sep 2020 14:10:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:10:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'UN UNK 2018'	Jennifer Molstead (b) (4)	26 Sep 2020 14:10:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	26 Sep 2020 14:10:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:10:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	26 Sep 2020 14:10:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Sep 2020 14:10:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Sep 2020 14:10:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 14:10:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 14:10:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 14:37:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	06 Oct 2020 14:37:16
Data point term sent to Coder	System	05 Oct 2020 16:10:05
User entered 'DOXYCYCLINE'	Traci Hull (b) (4)	05 Oct 2020 16:09:30
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'WORSENING OF EMPHYSEMA'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '100'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'twice daily (BID)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4)	05 Oct 2020 16:09:30
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	05 Oct 2020 16:09:30
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4)	05 Oct 2020 16:09:30
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '1 Oct 2020'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Traci Hull (b) (4)	05 Oct 2020 16:09:30
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)' reason for change: New Information	Traci Hull (b) (4)	13 Oct 2020 14:59:14
User entered 'Yes (Y)'	Traci Hull (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '12 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	13 Oct 2020 14:59:14
User entered empty.	Traci Hull (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 16:09:30

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:27:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:27:18
Data point term sent to Coder	System	05 Oct 2020 16:14:12
User entered 'PREDNISONE'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4)	05 Oct 2020 16:13:27
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'WORSENING OF EMPHYSEMA'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '30'	Traci Hull (b) (4)	05 Oct 2020 16:13:27
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4)	05 Oct 2020 16:13:27
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4)	05 Oct 2020 16:13:27
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	05 Oct 2020 16:13:27
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4)	05 Oct 2020 16:13:27
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '01 Oct 2020'	Traci Hull (b) (4)	05 Oct 2020 16:13:27
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Traci Hull (b) (4)	05 Oct 2020 16:13:27
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4)	05 Oct 2020 16:13:27
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '4 Oct 2020'	Traci Hull (b) (4)	05 Oct 2020 16:13:27
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 16:13:27

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:27:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:27:18
Data point term sent to Coder	System	05 Oct 2020 16:15:14
User entered 'PREDNISONE'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'WORSENING OF EMPHYSEMA'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '25'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4)	05 Oct 2020 16:14:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4)	05 Oct 2020 16:14:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	05 Oct 2020 16:14:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4)	05 Oct 2020 16:14:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '5 Oct 2020'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Traci Hull (b) (4)	05 Oct 2020 16:14:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	06 Oct 2020 15:12:49
User entered '6 Oct 2020' reason for change: Data Entry Error	Traci Hull (b) (4)	06 Oct 2020 15:12:49
User opened query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	05 Oct 2020 16:14:33
User entered '06 Oct 2020'	System	05 Oct 2020 16:14:33
	Traci Hull (b) (4)	05 Oct 2020 16:14:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4)	05 Oct 2020 16:14:33
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 16:14:33

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 16:07:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	09 Oct 2020 16:07:29
Data point term sent to Coder	System	09 Oct 2020 15:29:53
User entered 'PREDNISONEE'	Traci Hull (b) (4)	09 Oct 2020 15:29:14
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'WORSENING OF EMPHYSEMA'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '20'	Traci Hull (b) (4)	09 Oct 2020 15:29:14
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4)	09 Oct 2020 15:29:14
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	09 Oct 2020 15:29:14
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4)	09 Oct 2020 15:29:14
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '7 Oct 2020'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Traci Hull (b) (4)	09 Oct 2020 15:29:14
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '8 Oct 2020'	Traci Hull (b) (4)	09 Oct 2020 15:29:14
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Oct 2020 15:29:14

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 15:01:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	13 Oct 2020 15:01:29
Data point term sent to Coder	System	13 Oct 2020 15:00:49
User entered 'PREDNISONE'	Traci Hull (b) (4)	13 Oct 2020 15:00:25
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'WORSENING OF EMPHYSEMA'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '15'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4)	13 Oct 2020 15:00:25
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '9 Oct 2020'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '10 Oct 2020'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 15:00:25

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 14:32:20
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 Oct 2020 14:32:20
Data point term sent to Coder	System	18 Oct 2020 14:23:14
User entered 'APIXABAN'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'WORSENING EMPHYSEMA'	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '5'	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'twice daily (BID)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Oct 2020 14:22:52

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Oct 2020 14:46:25
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 Oct 2020 14:46:25
Data point term sent to Coder	System	18 Oct 2020 14:26:17
User entered 'CEFTRIAXONE'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'WORSENING EMPHYSEMA'	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '1'	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'g (g)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	19 Oct 2020 11:44:09
User entered '01 Oct 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4)	19 Oct 2020 11:44:09
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	18 Oct 2020 14:25:18
	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User closed query 'Per CDM : If not Ongoing, End date (dd MMM yyyy is updated however the Ongoing field is left blank. Kindly update as appropriate else clarify in query response.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 13:52:35
Query 'Per CDM : If not Ongoing, End date (dd MMM yyyy is updated however the Ongoing field is left blank. Kindly update as appropriate else clarify in query response.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	04 Nov 2020 18:37:04
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	04 Nov 2020 18:36:57
User opened query 'Per CDM : If not Ongoing, End date (dd MMM yyyy is updated however the Ongoing field is left blank. Kindly update as appropriate else clarify in query response.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 04:10:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 11:45:48
Query 'Data is required. Please complete.' answered with 'data updated' (Site from System).	Tammy Kohn (b) (4)	19 Oct 2020 11:44:43
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Oct 2020 14:25:18
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Oct 2020 14:25:18

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Oct 2020 14:47:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Oct 2020 14:47:25
Data point term sent to Coder	System	18 Oct 2020 14:29:18
User entered 'METHYLPREDNISOLONE'	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'WORSENING EMPHYSEMA'	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '40'	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'twice daily (BID)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:28:42

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	18 Oct 2020 14:28:42

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Oct 2020 14:28:42

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Oct 2020 14:28:42

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFDINIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 21:38:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	19 Oct 2020 21:38:34
Data point term sent to Coder	System	19 Oct 2020 21:37:52
User entered 'CEFDINIR'	Traci Hull (b) (4)	19 Oct 2020 21:37:45
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'PNEUMONIA'	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '300'	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'twice daily (BID)'	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	19 Oct 2020 21:37:45
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '17 Oct 2020'	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Traci Hull (b) (4)	19 Oct 2020 21:37:45
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 21:37:45

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:29:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:29:51
Data point term sent to Coder	System	29 Oct 2020 22:52:05
User entered 'Oxygen'	Jennifer Molstead (b) (4) (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Worsening Emphysema'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '3'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Liters'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'other (OTHER)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'continous'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Nasal (NASAL)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '17 Oct 2020'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:51:34

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 23:34:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	29 Oct 2020 23:34:46
Data point term sent to Coder	System	29 Oct 2020 22:53:06
User entered 'Azithromycin'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Worsening Emphysema'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '500'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered empty.	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '0'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered '17 Oct 2020'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23
	(b) (4)	

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:22:42
User entered 'No (N)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 22:52:23

US3402042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:23:19

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4)	18 Oct 2020 14:13:57
User entered 'No (N)'	Traci Hull (b) (4)	03 Sep 2020 14:39:03

US3402042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:23:19

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:14:26

US3402042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:23:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'CHEST XRAY'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:14:26

US3402042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:23:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4)	18 Oct 2020 14:14:26
	(b) (4)	

US3402042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:23:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:14:26

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'USA-US059-2020-MRNA-1273-P301000006'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Frank'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Eder'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '1290 Upper Front Street'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Binghamton'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'NY'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '13901'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:54:35
User entered 'US'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Nov 2020 14:18:12
User entered '3'	System	30 Oct 2020 15:16:32
User entered '2'	System	19 Oct 2020 16:55:04
User entered '1'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'USA-US059-2020-MRNA-1273-P301000006'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Frank'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Eder'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '1290 Upper Front Street'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Binghamton'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'NY'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '13901'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:54:35
User entered 'US'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Nov 2020 14:18:12
User entered '3'	System	30 Oct 2020 15:16:32
User entered '2'	System	19 Oct 2020 16:55:04
User entered '1'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:23:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
User entered '14/Oct/2020 13:44'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:23:19

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 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:54:35
User entered '1'	(b) (4), (b) (6)	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'USA-US059-2020-MRNA-1273-P301000006'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Frank'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Eder'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '1290 Upper Front Street'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Binghamton'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'NY'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '13901'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:54:35
User entered 'US'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Nov 2020 14:18:12
User entered '3'	System	30 Oct 2020 15:16:32
User entered '2'	System	19 Oct 2020 16:55:04
User entered '1'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:23:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
User entered '19/Oct/2020 16:55'	System	19 Oct 2020 16:55:04

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:23:19

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 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:56:39
User entered '1'	(b) (4), (b) (6)	19 Oct 2020 16:55:04

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'USA-US059-2020-MRNA-1273-P301000006'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Frank'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Eder'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '1290 Upper Front Street'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Binghamton'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'NY'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '13901'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:54:35
User entered 'US'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Nov 2020 14:18:12
User entered '3'	System	30 Oct 2020 15:16:32
User entered '2'	System	19 Oct 2020 16:55:04
User entered '1'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:23:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
User entered '30/Oct/2020 15:16'	System	30 Oct 2020 15:16:32

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:23:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 14:17:59
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
User entered '1'	(b) (4), (b) (6)	30 Oct 2020 15:16:32

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'USA-US059-2020-MRNA-1273-P301000006'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Yes (Y)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'No (N)'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Frank'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Eder'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '1290 Upper Front Street'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'Binghamton'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered 'NY'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:44:23
User entered '13901'	System	14 Oct 2020 13:43:03

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 04:15:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:54:35
User entered 'US'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Nov 2020 14:18:12
User entered '3'	System	30 Oct 2020 15:16:32
User entered '2'	System	19 Oct 2020 16:55:04
User entered '1'	System	14 Oct 2020 13:44:29

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:23:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '12/Nov/2020 14:18'	System	12 Nov 2020 14:18:12

US3402042

Folder: SAE USA-US059-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:23:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 14:18:12