

US3402139 (Prod: Meridian Clinical Research, LLC)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:23:58

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US3402139

Form: Participant Creation

Generated On: 26 Nov 2020 09:23:58

[Participant ID](#)

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

US3402139

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:58

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	55
Age Units	YEARS
Age (Derived)	55
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 09:23:58

Date of Informed Consent (<i>dd MMM yyyy</i>)	01 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☒
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:23:58

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:23:58

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:58

Condition	ENVIRONMENTAL ALLERGIES
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 (2)

Generated On: 26 Nov 2020 09:23:58

Condition	MIGRAINE HEADACHES
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 (3)

Generated On: 26 Nov 2020 09:23:58

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

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:58

Condition	LEFT KNEE ARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	01 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:45 (24 HR)
Vital Signs Date and Time (derived)	01 AUG 2020 09:45
Height (<i>xxx.x</i>)	169.5 cm
Weight (<i>xxx.x</i>)	71.2 kg
BMI (<i>xxx.x</i>)	24.78224 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	36.8 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>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:58

Date of assessment (<i>dd MMM yyyy</i>)	01 AUG 2020
Is the participant of childbearing potential?	Yes ☐
	No ☒
If No, what is the reason?	Surgically sterile ☐
	Post-menopausal ☒
	Partner medically sterile ☐
	Not reached age of Menarche ☐
	Other ☐
If Partner medically sterile or Other, specify _____	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 2015
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

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	True
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)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:58

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

What was the participant's randomization number? 100518

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 09:23:58

Height	169.5 cm
Weight	71.2 kg

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

Height	169.5 cm
Weight	71.2 kg
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	01 AUG 2020
Time of assessment (00:00-23:59)	09:45 (24 HR)
Vital Signs Date and Time (derived)	01 AUG 2020 09:45
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 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 09:23:58

Height	169.5 cm
Weight	71.2 kg
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	01 AUG 2020
Time of assessment (00:00-23:59)	10:57 (24 HR)
Vital Signs Date and Time (derived)	01 AUG 2020 10:57
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

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) 01 AUG 2020

What was the treatment time? (00:00-23:59) 10:25 (24 HR)

Treatment Date and Time (derived) 01 AUG 2020 10:25

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 09:23:58

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

01 AUG 2020

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

10:10 (24 HR)

Collection date and time (derived)

01 AUG 2020 10:10

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:58

Collection date (<i>dd MMM yyyy</i>)			01 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	09:55	01 AUG 2020 09:55
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

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 09:23:58

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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 10:59

PC Open Date & Time

01 AUG 2020 10:45

PC Close Date & Time

01 AUG 2020 13:15

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

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

98.7 °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

01 AUG 2020 20:37

PC Open Date & Time

01 AUG 2020 14:10

PC Close Date & Time

02 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:58

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

02 AUG 2020 12:00

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:58

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

97.5 °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

03 AUG 2020 12:35

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

04 AUG 2020 12:02

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:58

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

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

05 AUG 2020 12:05

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:58

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

06 AUG 2020 12:28

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

07 AUG 2020 13:02

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 10:59

PC Open Date & Time

01 AUG 2020 10:45

PC Close Date & Time

01 AUG 2020 13:15

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 20:38

PC Open Date & Time

01 AUG 2020 14:10

PC Close Date & Time

02 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 12:01

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 12:36

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 12:02

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 12:05

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 12:28

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 13:02

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

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

No ☒

Yes ☐

PC Time stamp	01 AUG 2020 11:00
PC Open Date & Time	01 AUG 2020 10:45
PC Close Date & Time	01 AUG 2020 13:15

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

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

No ☒

Yes ☐

PC Time stamp	01 AUG 2020 20:38
PC Open Date & Time	01 AUG 2020 14:10
PC Close Date & Time	02 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

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 ☒

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

Yes ☐	
PC Time stamp	02 AUG 2020 12:01
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

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 ☒

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

Yes ☐	
PC Time stamp	03 AUG 2020 12:36
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

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 ☒

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

Yes ☐	
PC Time stamp	04 AUG 2020 12:02
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

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 ☒

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

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

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

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 ☒

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

Yes ☐	
PC Time stamp	06 AUG 2020 12:28
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

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 ☒

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

Yes ☐	
PC Time stamp	07 AUG 2020 13:02
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3402139

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402139

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402139

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

Was Contact Attempted?

Yes ☒

No ☐

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

15 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402139

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402139

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402139

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402139

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	08:14 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 08:14
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	09:12 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 09:12
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3402139

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

US3402139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 08:40 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 08:40

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

US3402139

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:58

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

31 AUG 2020

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

08:33 (24 HR)

Collection date and time (derived)

31 AUG 2020 08:33

US3402139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:58

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:35	31 AUG 2020 08:35
Nasopharyngeal Swab 2	No		

US3402139

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

31 AUG 2020 09:11

PC Open Date & Time

31 AUG 2020 09:00

PC Close Date & Time

31 AUG 2020 11:30

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

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

97.9 °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

31 AUG 2020 13:25

PC Open Date & Time

31 AUG 2020 12:25

PC Close Date & Time

01 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	99.2 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

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

PC Time Stamp	01 SEP 2020 16:11
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

02 SEP 2020 13:52

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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 SEP 2020 12:41

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:58

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

97.4 °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

04 SEP 2020 12:02

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:58

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

97.1 °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

05 SEP 2020 12:04

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 20:41

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

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

31 AUG 2020 09:12

PC Open Date & Time

31 AUG 2020 09:00

PC Close Date & Time

31 AUG 2020 11:30

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

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

31 AUG 2020 13:26

PC Open Date & Time

31 AUG 2020 12:25

PC Close Date & Time

01 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:58

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

01 SEP 2020 16:13

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:58

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

02 SEP 2020 13:50

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:58

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

03 SEP 2020 12:39

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:58

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

04 SEP 2020 12:02

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:58

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

05 SEP 2020 12:04

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:58

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

06 SEP 2020 20:41

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 09:13
PC Open Date & Time	31 AUG 2020 09:00
PC Close Date & Time	31 AUG 2020 11:30

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 13:26
PC Open Date & Time	31 AUG 2020 12:25
PC Close Date & Time	01 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

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 ☒

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

Yes ☐	
PC Time stamp	01 SEP 2020 16:13
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

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 ☒

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

Yes ☐	
PC Time stamp	02 SEP 2020 13:50
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

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 ☒

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

Yes ☐	
PC Time stamp	03 SEP 2020 12:40
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

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 ☒

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

Yes ☐	
PC Time stamp	04 SEP 2020 12:02
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

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 ☒

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

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

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

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 ☒

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

Yes ☐	
PC Time stamp	06 SEP 2020 20:42
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3402139

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

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

US3402139

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402139

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402139

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402139

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

Was Contact Attempted?

Yes ☒

No ☐

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

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402139

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402139

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	25 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	25 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:07 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 13:07
Temperature (<i>xxx.x</i>)	98.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	65 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402139

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:58

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.

US3402139

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:58

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	25 SEP 2020
Collection time (<i>00:00-23:59</i>)	13:13 (24 HR)
Collection date and time (derived)	25 SEP 2020 13:13

US3402139

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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	02 OCT 2020 10:50:46
Patient Cloud Open Date & Time	01 OCT 2020 00:01
Patient Cloud Close Date & Time	05 OCT 2020 23:59

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 OCT 2020 07:32:16

Patient Cloud Open Date & Time

08 OCT 2020 00:01

Patient Cloud Close Date & Time

12 OCT 2020 23:59

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

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

Date and time of submission

18 OCT 2020 07:47:59

Patient Cloud Open Date & Time

15 OCT 2020 00:01

Patient Cloud Close Date & Time

19 OCT 2020 23:59

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

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

Date and time of submission

30 OCT 2020 10:04:11

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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	07 NOV 2020 07:43:15
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

16 NOV 2020 16:53:13

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2020 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2020 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2020 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2020 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2020 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2020 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2020 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2020 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 16:50:59
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

DAY 117

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

27 NOV 2020 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2020 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

11 DEC 2020 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

18 DEC 2020 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

25 DEC 2020 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

01 JAN 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JAN 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JAN 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JAN 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JAN 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

05 FEB 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

12 FEB 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

19 FEB 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

26 FEB 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAR 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAR 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAR 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAR 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 APR 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 APR 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 APR 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 APR 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 APR 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

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03 SEP 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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°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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

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28 JAN 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

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04 FEB 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

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11 FEB 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

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18 FEB 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

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25 FEB 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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°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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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04 MAR 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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Date and time of submission

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07 MAR 2022 00:01

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11 MAR 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

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18 MAR 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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25 MAR 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

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01 APR 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2022 00:01

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08 APR 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2022 00:01

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15 APR 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 APR 2022 00:01

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22 APR 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2022 00:01

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29 APR 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

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20 MAY 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2022 00:01

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15 JUL 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

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22 JUL 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2022 00:01

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29 JUL 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3402139

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

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

US3402139

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402139

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:58

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

US3402139

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:23:58

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3402139

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:23:58

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3402139

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:58

AEID	USA-US059-2020-MRNA-1273-P30 1000014
Adverse event	WORSENING LEFT KNEE ARTHRITIS
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)	09 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	14 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	14 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102)

337 of 2054

US3402139

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:58

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

US3402139

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:58

SUBJECT WAS ADMITTED
12OCT2020 FOR A LEFT KNEE
REPLACEMENT. SUBJECT WAS
DISCHARGED 14OCT2020.
SUBJECT DID HAVE COVID 19
TESTING DONE WHICH WAS
NEGATIVE. SUBJECT DID HAVE
COMPLETE BLOOD COUNT
WHICH SHOWED THAT THE
HEMAGLOBIN WAS 10.8 ON
13NOV2020, AND 11.1
14NOV2020 BOTH OF WHICH
WERE LOW THE NORMAL
RANGE IS 12.0-16.0.

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

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:23:58

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

Yes ☒

No ☐

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

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

Name of Medication	LEVOCETIRIZINE
Prophylaxis	Yes ☐ No ☒
Indication	ENVIRONMENTAL ALLERGIES
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 ☐

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN MAY 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

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

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

	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 2007
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

Name of Medication	TURMERIC CURCUMIN
Prophylaxis	Yes ☒ No ☐
Indication	NUTRITIONAL SUPPLEMENT
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 ☐

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

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

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

Name of Medication	MAGNESIUM OXIDE
Prophylaxis	Yes ☒ No ☐
Indication	NUTRITIONAL SUPPLEMENT
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 ☐

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

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

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes ☒ No ☐
Indication	MILD PAIN AT INJECTION SITE ON DAY 2 OF DIARY AND BODY ACHES
Dose per administration	1000
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		02 SEP 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	☐

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

Name of Medication	AMBIEN
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING LEFT KNEE ARTHRITIS
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 ☐

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

	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)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

Name of Medication ATARAX - HYDROXYZINE
HYDROCHLORIDE

Prophylaxis Yes ☐
No ☒

Indication WORSENING LEFT KNEE
ARTHRITIS

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY THREE HOUR AS
NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

v6.020 DTW (1102)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

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

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

	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)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy) 14 OCT 2020		
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

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

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

	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)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

Name of Medication	ECOTRIN
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING LEFT KNEE ARTHRITIS
Dose per administration	325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

	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)		12 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 14 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

Name of Medication	FAMOTIDINE
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING LEFT KNEE ARTHRITIS
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

	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)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

Name of Medication	FAMOTIDINE
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING LEFT KNEE ARTHRITIS
Dose per administration	20/2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	MG/ML
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

	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)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

Name of Medication	FENTANYL
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING LEFT KNEE ARTHRITIS
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

	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)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

Name of Medication	FERROUS SULFATE
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING LEFT KNEE ARTHRITIS
Dose per administration	325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

	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)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 14 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

Name of Medication	FLEET ENEMA
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING LEFT KNEE ARTHRITIS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	BOTTLE
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

	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)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

Name of Medication	GABAPENTIN
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING LEFT KNEE ARTHRITIS
Dose per administration	400
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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

	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)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

Name of Medication	LACTATED RINGERS
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING LEFT KNEE ARTHRITIS
Dose per administration	1000
Dose unit	mg ☐ ug ☐ mL ☒ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	CONTINUOUS Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

	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)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

Name of Medication	LOVENOX
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING LEFT KNEE ARTHRITIS
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 ☐

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

	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)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

Name of Medication	MILK OF MAGNESIA
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING LEFT KNEE ARTHRITIS
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 ☐

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

	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)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

Name of Medication	MORPHINE
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING LEFT KNEE ARTHRITIS
Dose per administration	6
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	EVERY 3 HOURS AS NEEDED Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

	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)		12 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

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

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

	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)		12 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

Name of Medication	HYDROCODONE/ACETAMINOP HEN
Prophylaxis	Yes ☐ No ☒
Indication	LEFT KNEE REPLACEMENT (ARTHROPLASTY)
Dose per administration	5/325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		22 OCT 2020
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

Name of Medication	AMOXICILLIN/CLAVULANIC ACID
Prophylaxis	Yes ☐ No ☒
Indication	LEFT KNEE REPLACEMENT (ARTHOPLASTY)
Dose per administration	125/875
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 ☐

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	22 OCT 2020	
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:23:58

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3402139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:23:58

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
12 OCT 2020	LEFT KNEE REPLACEMENT	Other	LEFT KNEE REPLACEMENT DUE TO LEFT KNEE ARTHRITIS
13 OCT 2020	COMPLETE BLOOD COUNT	Adverse Event	
14 OCT 2020	COMPLETE BLOOD COUNT	Adverse Event	

US3402139

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:23:58

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

US3402139

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:23:58

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 ☐

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

SAEID	USA-US059-2020-MRNA-1273-P301000014
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

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:23:58

SAEID	USA-US059-2020-MRNA-1273-P301000014
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)	27/OCT/2020 10:25
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

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:23:58

SAEID	USA-US059-2020-MRNA-1273-P301000014
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)	09/NOV/2020 14:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:23:58

SAEID	USA-US059-2020-MRNA-1273-P301000014
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)	18/NOV/2020 09:45
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

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:23:58

SAEID	USA-US059-2020-MRNA-1273-P301000014
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)	24/NOV/2020 08:43
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

US3402139 (Prod: Meridian Clinical Research, LLC)

US3402139

Form: Participant Creation

Generated On: 26 Nov 2020 09:23:58

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3402139'	RWS_ENDPOINT ENDPOINT (b) (4) 	01 Aug 2020 13:54:06

US3402139

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:20:18

US3402139

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '01 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	01 Aug 2020 13:54:07

US3402139

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

[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)	01 Aug 2020 16:20:18

US3402139

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	01 Aug 2020 16:20:18

US3402139

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered (b) (6) 1965'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Aug 2020 13:54:08

US3402139

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:58

[Age](#)

Audit	User	Time (GMT)
User entered '55'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:20:34

US3402139

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:58

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	01 Aug 2020 16:20:34

US3402139

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:58

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '55'	System	01 Aug 2020 14:28:53

US3402139

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:58

Sex

Audit	User	Time (GMT)
User entered 'Female (F)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:20:34

US3402139

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:58

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:20:34

US3402139

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:58

White

Audit	User	Time (GMT)
User entered '1'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:20:34

US3402139

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:58

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:20:34

US3402139

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:58

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:20:34

US3402139

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:58

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:20:34

US3402139

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:58

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:20:34

US3402139

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:58

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:20:34

US3402139

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:58

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:20:34

US3402139

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:58

Unknown

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:20:34

US3402139

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:58

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:20:34

US3402139

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '01 Aug 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 12:17:46
User entered '1 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 14:28:53

US3402139

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	01 Aug 2020 14:28:53

US3402139

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '2020'	System	01 Aug 2020 14:28:53

US3402139

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:58

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 14:28:53

US3402139

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 14:28:53

US3402139

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 14:28:53

US3402139

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:58

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 14:28:53

US3402139

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:58

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 14:28:53

US3402139

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:58

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Aug 2020 13:54:07

US3402139

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:58

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 14:28:58

US3402139

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 14:28:58

US3402139

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:23:58

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:22:23

US3402139

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4)	01 Aug 2020 16:26:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Aug 2020 16:26:04
Data point term sent to Coder	System	01 Aug 2020 16:24:35
User entered 'ENVIRONMENTAL ALLERGIES'	Tarin Gordon (b) (4)	01 Aug 2020 16:24:26

US3402139

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:24:26

US3402139

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:24:26

US3402139

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:24:26

US3402139

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:24:26

US3402139

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:24:26

US3402139

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	01 Aug 2020 16:24:26

US3402139

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '2010'	System	01 Aug 2020 16:24:26

US3402139

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:24:26

US3402139

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:24:26

US3402139

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 16:32:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 16:32:07
Data point term sent to Coder	System	01 Aug 2020 16:30:37
User entered 'MIGRAINE HEADACHES'	Tarin Gordon (b) (4)	01 Aug 2020 16:29:40

US3402139

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'UN UNK 1990'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:29:40

US3402139

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:29:40

US3402139

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:29:40

US3402139

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:29:40

US3402139

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:29:40

US3402139

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	01 Aug 2020 16:29:40

US3402139

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '1990'	System	01 Aug 2020 16:29:40

US3402139

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:29:40

US3402139

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:29:40

US3402139

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 16:32:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	01 Aug 2020 16:32:07
Data point term sent to Coder	System	01 Aug 2020 16:30:36
User entered 'POST-MENOPAUSAL'	Tarin Gordon (b) (4)	01 Aug 2020 16:30:33
	(b) (4)	

US3402139

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:30:33

US3402139

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:30:33

US3402139

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:30:33

US3402139

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:30:33

US3402139

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:30:33

US3402139

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	01 Aug 2020 16:30:33

US3402139

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '2015'	System	01 Aug 2020 16:30:33

US3402139

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:30:33

US3402139

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:30:33

US3402139

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	07 Nov 2020 13:22:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Nov 2020 13:22:30
Data point term sent to Coder	System	07 Nov 2020 13:21:33
User entered 'Left knee arthritis'	Jennifer Molstead (b) (4)	07 Nov 2020 13:20:55
	(b) (4)	

US3402139

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'un UNK 2002'	Jennifer Molstead (b) (4)	07 Nov 2020 13:20:55
	(b) (4)	

US3402139

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Molstead (b) (4)	07 Nov 2020 13:20:55
	(b) (4)	

US3402139

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	07 Nov 2020 13:20:55
	(b) (4)	

US3402139

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	07 Nov 2020 13:20:55
	(b) (4)	

US3402139

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	07 Nov 2020 13:20:55

US3402139

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	07 Nov 2020 13:20:55

US3402139

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '2002'	System	07 Nov 2020 13:20:55

US3402139

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 13:20:55

US3402139

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered empty.	System	07 Nov 2020 13:20:55

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:23:24

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Aug 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 12:18:12
User entered '1 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:23:24

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '09:45'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:23:24

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '01 Aug 2020 09:45'	System	11 Nov 2020 12:18:12
User entered '1 Aug 2020 09:45'	System	01 Aug 2020 16:23:24

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '169.5' cm	Tarin Gordon (b) (4)	01 Aug 2020 16:23:24
DataPoint set to visible.	(b) (4) System	01 Aug 2020 14:28:58

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '71.2' kg	Tarin Gordon (b) (4)	01 Aug 2020 16:23:24
DataPoint set to visible.	(b) (4) System	01 Aug 2020 14:28:58

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '24.78224'	System	16 Sep 2020 23:40:18
User entered '24.8'	System	01 Aug 2020 16:23:24
DataPoint set to visible.	System	01 Aug 2020 14:28:58

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	01 Aug 2020 16:23:24
DataPoint set to visible.	System	01 Aug 2020 14:28:58

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:23:24

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:23:24

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:23:24

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:23:24

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Aug 2020 16:23:24

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '14'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:23:24

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Aug 2020 16:23:24

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '127'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:23:24

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 16:23:24

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '79'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:23:24

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 16:23:24

US3402139

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:30:54

US3402139

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '01 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:18:23
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4)	
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	06 Sep 2020 12:18:04
User entered '1 Aug 2020'	Tarin Gordon (b) (4)	01 Aug 2020 16:30:54

US3402139

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Aug 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 12:18:39
User entered '1 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:31:12

US3402139

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:31:12

US3402139

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:58

If No, what is the reason?

Audit	User	Time (GMT)
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:31:12

US3402139

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:31:12

US3402139

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:31:12

US3402139

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:58

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:31:12

US3402139

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:31:12

US3402139

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:58

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:31:12

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

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)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

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)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

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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)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

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)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

[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)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

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)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

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)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

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)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

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)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

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)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

No Risk Identified

Audit	User	Time (GMT)
User entered '1'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

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)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

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)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

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)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:33:25

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:58

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:33:25

US3402139

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:33:56

US3402139

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '01 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:18:59
User entered '1 Aug 2020'	Tarin Gordon (b) (4)	01 Aug 2020 16:33:56

US3402139

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

[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)	01 Aug 2020 16:33:56

US3402139

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	01 Aug 2020 16:33:56

US3402139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '01 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	01 Aug 2020 13:59:06

US3402139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:58

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 01:36:09
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:36:08
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 13:59:06
User entered '100518' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Aug 2020 13:59:06

US3402139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) 	01 Aug 2020 13:59:06

US3402139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:34:51

US3402139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:34:51

US3402139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:34:51

US3402139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:58

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:34:51

US3402139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:58

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:34:51

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:58

Height

Audit	User	Time (GMT)
User entered '169.5' cm	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:58

Weight

Audit	User	Time (GMT)
User entered '71.2' kg	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:58

Height

Audit	User	Time (GMT)
User entered '169.5' cm	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:58

Weight

Audit	User	Time (GMT)
User entered '71.2' kg	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Aug 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 12:19:24
User entered '1 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '09:45'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '01 Aug 2020 09:45'	System	11 Nov 2020 12:19:24
User entered '1 Aug 2020 09:45'	System	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '14'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '127'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '79'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:58

Height

Audit	User	Time (GMT)
User entered '169.5' cm	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:58

Weight

Audit	User	Time (GMT)
User entered '71.2' kg	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Aug 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 12:19:24
User entered '1 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 19:36:25
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 MIN' (Site from System).	Tarin Gordon (b) (4)	01 Aug 2020 16:38:27
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).		01 Aug 2020 16:37:46
User entered '10:57'	Tarin Gordon (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '01 Aug 2020 10:57'	System	11 Nov 2020 12:19:24
User entered '1 Aug 2020 10:57'	System	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '87'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '14'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '130'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '87'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 16:37:46

US3402139

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:58

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:38:37

US3402139

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '01 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:19:36
User entered '1 Aug 2020'	Tarin Gordon (b) (4)	01 Aug 2020 16:38:37

US3402139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 14:29:27

US3402139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 14:29:27

US3402139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

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)	01 Aug 2020 14:29:27

US3402139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	01 Aug 2020 14:29:27

US3402139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '01 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:19:52
User entered '1 Aug 2020'	Tarin Gordon (b) (4)	01 Aug 2020 14:29:27

US3402139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '10:25'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 14:29:27

US3402139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '01 Aug 2020 10:25'	System	11 Nov 2020 12:19:52
User entered '1 Aug 2020 10:25'	System	01 Aug 2020 14:29:27

US3402139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 14:29:27

US3402139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	01 Aug 2020 14:29:27

US3402139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	01 Aug 2020 14:29:27

US3402139

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:39:50

US3402139

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Aug 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 12:20:04
User entered '1 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:39:50

US3402139

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:10'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:39:50

US3402139

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '01 Aug 2020 10:10'	System	11 Nov 2020 12:20:04
User entered '1 Aug 2020 10:10'	System	01 Aug 2020 16:39:50

US3402139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '01 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:20:19
User entered '1 Aug 2020'	Tarin Gordon (b) (4)	01 Aug 2020 16:39:18

US3402139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:58

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:39:18

US3402139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:39:18

US3402139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '09:55'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:39:18

US3402139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '01 Aug 2020 09:55'	System	11 Nov 2020 12:20:19
User entered '1 Aug 2020 09:55'	System	01 Aug 2020 16:39:18

US3402139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:58

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:39:18

US3402139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:39:18

US3402139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:39:18

US3402139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:39:18

US3402139

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:39:36

US3402139

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 16:39:36

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T10:58:49', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1849e445-003f-4146-8008-a666886025da'	System	01 Aug 2020 14:59:07
User entered 'Yes (Y)'	System	01 Aug 2020 14:59:07

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T10:58:54', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1849e445-003f-4146-8008-a666886025da'	System	01 Aug 2020 14:59:07
User entered '98.3'	System	01 Aug 2020 14:59:07

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T10:59:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1849e445-003f-4146-8008-a666886025da'	System	01 Aug 2020 14:59:07
User entered 'No (N)'	System	01 Aug 2020 14:59:07

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T10:59:04', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1849e445-003f-4146-8008-a666886025da'	System	01 Aug 2020 14:59:07
User entered '01 Aug 2020 10:59'	System	01 Aug 2020 14:59:07

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 10:45'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 13:15'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:37:31', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '17ff2a52-becc-4cbc-8263-b7b48912971d'	System	02 Aug 2020 00:37:51
User entered 'Yes (Y)'	System	02 Aug 2020 00:37:51

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:37:39', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '17ff2a52-becc-4cbc-8263-b7b48912971d'	System	02 Aug 2020 00:37:51
User entered '98.7'	System	02 Aug 2020 00:37:51

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:37:43', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '17ff2a52-becc-4cbc-8263-b7b48912971d'	System	02 Aug 2020 00:37:51
User entered 'No (N)'	System	02 Aug 2020 00:37:51

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:37:46', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '17ff2a52-becc-4cbc-8263-b7b48912971d'	System	02 Aug 2020 00:37:51
User entered '01 Aug 2020 20:37'	System	02 Aug 2020 00:37:51

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 14:10'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 2'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:00:44', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '287c9444-2e1b-4414-98cc-abb8ef397d1b'	System	02 Aug 2020 16:00:56
User entered 'Yes (Y)'	System	02 Aug 2020 16:00:56

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:00:48', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '287c9444-2e1b-4414-98cc-abb8ef397d1b'	System	02 Aug 2020 16:00:56
User entered '98.3'	System	02 Aug 2020 16:00:56

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:00:51', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '287c9444-2e1b-4414-98cc-abb8ef397d1b'	System	02 Aug 2020 16:00:56
User entered 'No (N)'	System	02 Aug 2020 16:00:56

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:00:54', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '287c9444-2e1b-4414-98cc-abb8ef397d1b'	System	02 Aug 2020 16:00:56
User entered '02 Aug 2020 12:00'	System	02 Aug 2020 16:00:56

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 3'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:35:16', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8b372f31-68f5-4782-9daf-3c95ed19b0a2'	System	03 Aug 2020 16:35:52
User entered 'Yes (Y)'	System	03 Aug 2020 16:35:52

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:35:42', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8b372f31-68f5-4782-9daf-3c95ed19b0a2'	System	03 Aug 2020 16:35:52
User entered '97.5'	System	03 Aug 2020 16:35:52

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:35:45', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8b372f31-68f5-4782-9daf-3c95ed19b0a2'	System	03 Aug 2020 16:35:52
User entered 'No (N)'	System	03 Aug 2020 16:35:52

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:35:50', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8b372f31-68f5-4782-9daf-3c95ed19b0a2'	System	03 Aug 2020 16:35:52
User entered '03 Aug 2020 12:35'	System	03 Aug 2020 16:35:52

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 4'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:01:59', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '13d7c822-a783-4be1-894f-56c472058035'	System	04 Aug 2020 16:02:14
User entered 'Yes (Y)'	System	04 Aug 2020 16:02:14

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:03', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '13d7c822-a783-4be1-894f-56c472058035'	System	04 Aug 2020 16:02:14
User entered '98.0'	System	04 Aug 2020 16:02:14

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:08', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '13d7c822-a783-4be1-894f-56c472058035'	System	04 Aug 2020 16:02:14
User entered 'No (N)'	System	04 Aug 2020 16:02:14

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:11', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '13d7c822-a783-4be1-894f-56c472058035'	System	04 Aug 2020 16:02:14
User entered '04 Aug 2020 12:02'	System	04 Aug 2020 16:02:14

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 5'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:04:53', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '37150400-9214-4d40-bd51-da645ea1e972'	System	05 Aug 2020 16:05:06
User entered 'Yes (Y)'	System	05 Aug 2020 16:05:06

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:04:57', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '37150400-9214-4d40-bd51-da645ea1e972'	System	05 Aug 2020 16:05:06
User entered '98.3'	System	05 Aug 2020 16:05:06

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:04:59', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '37150400-9214-4d40-bd51-da645ea1e972'	System	05 Aug 2020 16:05:06
User entered 'No (N)'	System	05 Aug 2020 16:05:06

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:02', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '37150400-9214-4d40-bd51-da645ea1e972'	System	05 Aug 2020 16:05:06
User entered '05 Aug 2020 12:05'	System	05 Aug 2020 16:05:06

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 6'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:14', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '3f4b4732-6051-4e75-b0b5-984b580e43ca'	System	06 Aug 2020 16:28:31
User entered 'Yes (Y)'	System	06 Aug 2020 16:28:31

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:22', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '3f4b4732-6051-4e75-b0b5-984b580e43ca'	System	06 Aug 2020 16:28:31
User entered '97.3'	System	06 Aug 2020 16:28:31

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:24', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '3f4b4732-6051-4e75-b0b5-984b580e43ca'	System	06 Aug 2020 16:28:31
User entered 'No (N)'	System	06 Aug 2020 16:28:31

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:28', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '3f4b4732-6051-4e75-b0b5-984b580e43ca'	System	06 Aug 2020 16:28:31
User entered '06 Aug 2020 12:28'	System	06 Aug 2020 16:28:31

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 7'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:21', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '31762feb-e5e1-4667-82d1-b0a3b587e1d7'	System	07 Aug 2020 17:02:34
User entered 'Yes (Y)'	System	07 Aug 2020 17:02:34

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:25', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '31762feb-e5e1-4667-82d1-b0a3b587e1d7'	System	07 Aug 2020 17:02:34
User entered '98.4'	System	07 Aug 2020 17:02:34

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:28', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '31762feb-e5e1-4667-82d1-b0a3b587e1d7'	System	07 Aug 2020 17:02:34
User entered 'No (N)'	System	07 Aug 2020 17:02:34

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:30', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '31762feb-e5e1-4667-82d1-b0a3b587e1d7'	System	07 Aug 2020 17:02:34
User entered '07 Aug 2020 13:02'	System	07 Aug 2020 17:02:34

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-01T10:59:11', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b4dac4b9-d355-4239-9d1c-ae7ea342345d'	System	01 Aug 2020 14:59:37
User entered 'None (1)'	System	01 Aug 2020 14:59:37

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T10:59:18', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b4dac4b9-d355-4239-9d1c-ae7ea342345d'	System	01 Aug 2020 14:59:37
User entered 'No (N)'	System	01 Aug 2020 14:59:37

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T10:59:24', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b4dac4b9-d355-4239-9d1c-ae7ea342345d'	System	01 Aug 2020 14:59:37
User entered 'No (N)'	System	01 Aug 2020 14:59:37

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-01T10:59:31', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b4dac4b9-d355-4239-9d1c-ae7ea342345d'	System	01 Aug 2020 14:59:37
User entered 'None (1)'	System	01 Aug 2020 14:59:37

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T10:59:34', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b4dac4b9-d355-4239-9d1c-ae7ea342345d'	System	01 Aug 2020 14:59:37
User entered '01 Aug 2020 10:59'	System	01 Aug 2020 14:59:37

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 10:45'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 13:15'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-01T20:37:55', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b5563a88-46b6-4fce-b761-d5de2853cb6a'	System	02 Aug 2020 00:38:12
User entered 'None (1)'	System	02 Aug 2020 00:38:12

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:37:59', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b5563a88-46b6-4fce-b761-d5de2853cb6a'	System	02 Aug 2020 00:38:12
User entered 'No (N)'	System	02 Aug 2020 00:38:12

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:02', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b5563a88-46b6-4fce-b761-d5de2853cb6a'	System	02 Aug 2020 00:38:12
User entered 'No (N)'	System	02 Aug 2020 00:38:12

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-01T20:38:05', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b5563a88-46b6-4fce-b761-d5de2853cb6a'	System	02 Aug 2020 00:38:12
User entered 'None (1)'	System	02 Aug 2020 00:38:12

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:07', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b5563a88-46b6-4fce-b761-d5de2853cb6a'	System	02 Aug 2020 00:38:12
User entered '01 Aug 2020 20:38'	System	02 Aug 2020 00:38:12

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 14:10'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 2'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-02T12:01:04', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c6b97058-d685-4251-a958-0bf2d4c7c5d1'	System	02 Aug 2020 16:01:23
User entered 'Does not interfere with activity (2)'	System	02 Aug 2020 16:01:23

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:07', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c6b97058-d685-4251-a958-0bf2d4c7c5d1'	System	02 Aug 2020 16:01:23
User entered 'No (N)'	System	02 Aug 2020 16:01:23

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:13', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c6b97058-d685-4251-a958-0bf2d4c7c5d1'	System	02 Aug 2020 16:01:23
User entered 'No (N)'	System	02 Aug 2020 16:01:23

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-02T12:01:18', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c6b97058-d685-4251-a958-0bf2d4c7c5d1'	System	02 Aug 2020 16:01:23
User entered 'None (1)'	System	02 Aug 2020 16:01:23

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:21', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c6b97058-d685-4251-a958-0bf2d4c7c5d1'	System	02 Aug 2020 16:01:23
User entered '02 Aug 2020 12:01'	System	02 Aug 2020 16:01:23

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 3'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-03T12:35:57', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f436026b-92cf-42c2-b753-ea26dab39b15'	System	03 Aug 2020 16:36:30
User entered 'None (1)'	System	03 Aug 2020 16:36:30

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:35:59', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f436026b-92cf-42c2-b753-ea26dab39b15'	System	03 Aug 2020 16:36:30
User entered 'No (N)'	System	03 Aug 2020 16:36:30

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:02', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f436026b-92cf-42c2-b753-ea26dab39b15'	System	03 Aug 2020 16:36:30
User entered 'No (N)'	System	03 Aug 2020 16:36:30

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-03T12:36:22', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f436026b-92cf-42c2-b753-ea26dab39b15'	System	03 Aug 2020 16:36:30
User entered 'None (1)'	System	03 Aug 2020 16:36:30

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:26', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f436026b-92cf-42c2-b753-ea26dab39b15'	System	03 Aug 2020 16:36:30
User entered '03 Aug 2020 12:36'	System	03 Aug 2020 16:36:30

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 4'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-04T12:02:16', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c068ccce-b121-41bf-bb7e-372940a8df0e'	System	04 Aug 2020 16:02:30
User entered 'None (1)'	System	04 Aug 2020 16:02:30

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:19', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c068ccce-b121-41bf-bb7e-372940a8df0e'	System	04 Aug 2020 16:02:30
User entered 'No (N)'	System	04 Aug 2020 16:02:30

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:23', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c068ccce-b121-41bf-bb7e-372940a8df0e'	System	04 Aug 2020 16:02:30
User entered 'No (N)'	System	04 Aug 2020 16:02:30

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-04T12:02:25', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c068ccce-b121-41bf-bb7e-372940a8df0e'	System	04 Aug 2020 16:02:30
User entered 'None (1)'	System	04 Aug 2020 16:02:30

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:27', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c068ccce-b121-41bf-bb7e-372940a8df0e'	System	04 Aug 2020 16:02:30
User entered '04 Aug 2020 12:02'	System	04 Aug 2020 16:02:30

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 5'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-05T12:05:06', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '479b3763-84ac-41f3-a658-1a5be329eb01'	System	05 Aug 2020 16:05:21
User entered 'None (1)'	System	05 Aug 2020 16:05:21

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:10', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '479b3763-84ac-41f3-a658-1a5be329eb01'	System	05 Aug 2020 16:05:21
User entered 'No (N)'	System	05 Aug 2020 16:05:21

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:13', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '479b3763-84ac-41f3-a658-1a5be329eb01'	System	05 Aug 2020 16:05:21
User entered 'No (N)'	System	05 Aug 2020 16:05:21

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-05T12:05:16', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '479b3763-84ac-41f3-a658-1a5be329eb01'	System	05 Aug 2020 16:05:21
User entered 'None (1)'	System	05 Aug 2020 16:05:21

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:18', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '479b3763-84ac-41f3-a658-1a5be329eb01'	System	05 Aug 2020 16:05:21
User entered '05 Aug 2020 12:05'	System	05 Aug 2020 16:05:21

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 6'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-06T12:28:31', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5e84def8-7c99-482d-b8e7-c4716fd01518'	System	06 Aug 2020 16:28:43
User entered 'None (1)'	System	06 Aug 2020 16:28:43

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:33', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5e84def8-7c99-482d-b8e7-c4716fd01518'	System	06 Aug 2020 16:28:43
User entered 'No (N)'	System	06 Aug 2020 16:28:43

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:35', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5e84def8-7c99-482d-b8e7-c4716fd01518'	System	06 Aug 2020 16:28:43
User entered 'No (N)'	System	06 Aug 2020 16:28:43

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-06T12:28:37', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5e84def8-7c99-482d-b8e7-c4716fd01518'	System	06 Aug 2020 16:28:43
User entered 'None (1)'	System	06 Aug 2020 16:28:43

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:38', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5e84def8-7c99-482d-b8e7-c4716fd01518'	System	06 Aug 2020 16:28:43
User entered '06 Aug 2020 12:28'	System	06 Aug 2020 16:28:43

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 7'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-07T13:02:34', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a78afc74-76e6-474b-b62b-6f0cb5d8d70c'	System	07 Aug 2020 17:02:43
User entered 'None (1)'	System	07 Aug 2020 17:02:43

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:36', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a78afc74-76e6-474b-b62b-6f0cb5d8d70c'	System	07 Aug 2020 17:02:43
User entered 'No (N)'	System	07 Aug 2020 17:02:43

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:37', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a78afc74-76e6-474b-b62b-6f0cb5d8d70c'	System	07 Aug 2020 17:02:43
User entered 'No (N)'	System	07 Aug 2020 17:02:43

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-07T13:02:39', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a78afc74-76e6-474b-b62b-6f0cb5d8d70c'	System	07 Aug 2020 17:02:43
User entered 'None (1)'	System	07 Aug 2020 17:02:43

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:41', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a78afc74-76e6-474b-b62b-6f0cb5d8d70c'	System	07 Aug 2020 17:02:43
User entered '07 Aug 2020 13:02'	System	07 Aug 2020 17:02:43

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T10:59:41', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b9df7cf2-3282-4bc7-a87f-372f5154ff00'	System	01 Aug 2020 15:00:19
User entered 'None (0)'	System	01 Aug 2020 15:00:19

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T11:00:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b9df7cf2-3282-4bc7-a87f-372f5154ff00'	System	01 Aug 2020 15:00:19
User entered 'None (0)'	System	01 Aug 2020 15:00:19

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T11:00:02', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b9df7cf2-3282-4bc7-a87f-372f5154ff00'	System	01 Aug 2020 15:00:19
User entered 'None (0)'	System	01 Aug 2020 15:00:19

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T11:00:05', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b9df7cf2-3282-4bc7-a87f-372f5154ff00'	System	01 Aug 2020 15:00:19
User entered 'None (0)'	System	01 Aug 2020 15:00:19

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T11:00:07', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b9df7cf2-3282-4bc7-a87f-372f5154ff00'	System	01 Aug 2020 15:00:19
User entered 'None (0)'	System	01 Aug 2020 15:00:19

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T11:00:09', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b9df7cf2-3282-4bc7-a87f-372f5154ff00'	System	01 Aug 2020 15:00:19
User entered 'None (0)'	System	01 Aug 2020 15:00:19

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-01T11:00:12', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b9df7cf2-3282-4bc7-a87f-372f5154ff00'	System	01 Aug 2020 15:00:19
User entered 'No (N)'	System	01 Aug 2020 15:00:19

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T11:00:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b9df7cf2-3282-4bc7-a87f-372f5154ff00'	System	01 Aug 2020 15:00:19
User entered '01 Aug 2020 11:00'	System	01 Aug 2020 15:00:19

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 10:45'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 13:15'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:13', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1d06e0a1-4aef-4ad7-887a-5d7a080e1655'	System	02 Aug 2020 00:38:37
User entered 'None (0)'	System	02 Aug 2020 00:38:37

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:16', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1d06e0a1-4aef-4ad7-887a-5d7a080e1655'	System	02 Aug 2020 00:38:37
User entered 'None (0)'	System	02 Aug 2020 00:38:37

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:19', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1d06e0a1-4aef-4ad7-887a-5d7a080e1655'	System	02 Aug 2020 00:38:37
User entered 'None (0)'	System	02 Aug 2020 00:38:37

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:22', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1d06e0a1-4aef-4ad7-887a-5d7a080e1655'	System	02 Aug 2020 00:38:37
User entered 'None (0)'	System	02 Aug 2020 00:38:37

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:24', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1d06e0a1-4aef-4ad7-887a-5d7a080e1655'	System	02 Aug 2020 00:38:37
User entered 'None (0)'	System	02 Aug 2020 00:38:37

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:27', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1d06e0a1-4aef-4ad7-887a-5d7a080e1655'	System	02 Aug 2020 00:38:37
User entered 'None (0)'	System	02 Aug 2020 00:38:37

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-01T20:38:31', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1d06e0a1-4aef-4ad7-887a-5d7a080e1655'	System	02 Aug 2020 00:38:37
User entered 'No (N)'	System	02 Aug 2020 00:38:37

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:33', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1d06e0a1-4aef-4ad7-887a-5d7a080e1655'	System	02 Aug 2020 00:38:37
User entered '01 Aug 2020 20:38'	System	02 Aug 2020 00:38:37

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 14:10'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 2'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:28', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0832cbaa-de2a-4488-a6ea-28f49ca61041'	System	02 Aug 2020 16:01:47
User entered 'None (0)'	System	02 Aug 2020 16:01:47

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:31', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0832cbaa-de2a-4488-a6ea-28f49ca61041'	System	02 Aug 2020 16:01:47
User entered 'None (0)'	System	02 Aug 2020 16:01:47

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:33', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0832cbaa-de2a-4488-a6ea-28f49ca61041'	System	02 Aug 2020 16:01:47
User entered 'None (0)'	System	02 Aug 2020 16:01:47

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:36', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0832cbaa-de2a-4488-a6ea-28f49ca61041'	System	02 Aug 2020 16:01:47
User entered 'None (0)'	System	02 Aug 2020 16:01:47

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:38', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0832cbaa-de2a-4488-a6ea-28f49ca61041'	System	02 Aug 2020 16:01:47
User entered 'None (0)'	System	02 Aug 2020 16:01:47

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:40', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0832cbaa-de2a-4488-a6ea-28f49ca61041'	System	02 Aug 2020 16:01:47
User entered 'None (0)'	System	02 Aug 2020 16:01:47

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-02T12:01:42', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0832cbaa-de2a-4488-a6ea-28f49ca61041'	System	02 Aug 2020 16:01:47
User entered 'No (N)'	System	02 Aug 2020 16:01:47

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86fffec3798)', Time: '2020-08-02T12:01:45', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0832cbaa-de2a-4488-a6ea-28f49ca61041'	System	02 Aug 2020 16:01:47
User entered '02 Aug 2020 12:01'	System	02 Aug 2020 16:01:47

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 3'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:29', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8143c872-d2d2-43db-be4b-23edee9aace4'	System	03 Aug 2020 16:36:49
User entered 'None (0)'	System	03 Aug 2020 16:36:49

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:31', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8143c872-d2d2-43db-be4b-23edee9aace4'	System	03 Aug 2020 16:36:49
User entered 'None (0)'	System	03 Aug 2020 16:36:49

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:33', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8143c872-d2d2-43db-be4b-23edee9aace4'	System	03 Aug 2020 16:36:49
User entered 'None (0)'	System	03 Aug 2020 16:36:49

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:35', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8143c872-d2d2-43db-be4b-23edee9aace4'	System	03 Aug 2020 16:36:49
User entered 'None (0)'	System	03 Aug 2020 16:36:49

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:37', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8143c872-d2d2-43db-be4b-23edee9aace4'	System	03 Aug 2020 16:36:49
User entered 'None (0)'	System	03 Aug 2020 16:36:49

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:39', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8143c872-d2d2-43db-be4b-23edee9aace4'	System	03 Aug 2020 16:36:49
User entered 'None (0)'	System	03 Aug 2020 16:36:49

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-03T12:36:42', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8143c872-d2d2-43db-be4b-23edee9aace4'	System	03 Aug 2020 16:36:49
User entered 'No (N)'	System	03 Aug 2020 16:36:49

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:44', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8143c872-d2d2-43db-be4b-23edee9aace4'	System	03 Aug 2020 16:36:49
User entered '03 Aug 2020 12:36'	System	03 Aug 2020 16:36:49

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 4'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:31', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4a972e63-17ee-4840-9e21-f01d69647974'	System	04 Aug 2020 16:02:59
User entered 'None (0)'	System	04 Aug 2020 16:02:59

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:33', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4a972e63-17ee-4840-9e21-f01d69647974'	System	04 Aug 2020 16:02:59
User entered 'None (0)'	System	04 Aug 2020 16:02:59

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:35', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4a972e63-17ee-4840-9e21-f01d69647974'	System	04 Aug 2020 16:02:59
User entered 'None (0)'	System	04 Aug 2020 16:02:59

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:37', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4a972e63-17ee-4840-9e21-f01d69647974'	System	04 Aug 2020 16:02:59
User entered 'None (0)'	System	04 Aug 2020 16:02:59

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:39', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4a972e63-17ee-4840-9e21-f01d69647974'	System	04 Aug 2020 16:02:59
User entered 'None (0)'	System	04 Aug 2020 16:02:59

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:41', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4a972e63-17ee-4840-9e21-f01d69647974'	System	04 Aug 2020 16:02:59
User entered 'None (0)'	System	04 Aug 2020 16:02:59

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-04T12:02:44', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4a972e63-17ee-4840-9e21-f01d69647974'	System	04 Aug 2020 16:02:59
User entered 'No (N)'	System	04 Aug 2020 16:02:59

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:55', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4a972e63-17ee-4840-9e21-f01d69647974'	System	04 Aug 2020 16:02:59
User entered '04 Aug 2020 12:02'	System	04 Aug 2020 16:02:59

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 5'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86fffec3798)', Time: '2020-08-05T12:05:22', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '78d6207e-f8a2-4554-802f-8d5fcc4110d1'	System	05 Aug 2020 16:05:37
User entered 'None (0)'	System	05 Aug 2020 16:05:37

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:23', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '78d6207e-f8a2-4554-802f-8d5fcc4110d1'	System	05 Aug 2020 16:05:37
User entered 'None (0)'	System	05 Aug 2020 16:05:37

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:25', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '78d6207e-f8a2-4554-802f-8d5fcc4110d1'	System	05 Aug 2020 16:05:37
User entered 'None (0)'	System	05 Aug 2020 16:05:37

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:27', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '78d6207e-f8a2-4554-802f-8d5fcc4110d1'	System	05 Aug 2020 16:05:37
User entered 'None (0)'	System	05 Aug 2020 16:05:37

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:29', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '78d6207e-f8a2-4554-802f-8d5fcc4110d1'	System	05 Aug 2020 16:05:37
User entered 'None (0)'	System	05 Aug 2020 16:05:37

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:31', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '78d6207e-f8a2-4554-802f-8d5fcc4110d1'	System	05 Aug 2020 16:05:37
User entered 'None (0)'	System	05 Aug 2020 16:05:37

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-05T12:05:33', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '78d6207e-f8a2-4554-802f-8d5fcc4110d1'	System	05 Aug 2020 16:05:37
User entered 'No (N)'	System	05 Aug 2020 16:05:37

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:35', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '78d6207e-f8a2-4554-802f-8d5fcc4110d1'	System	05 Aug 2020 16:05:37
User entered '05 Aug 2020 12:05'	System	05 Aug 2020 16:05:37

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 6'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:42', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5a1660b3-9112-4d4a-9baa-ee8edb66b7a3'	System	06 Aug 2020 16:29:01
User entered 'None (0)'	System	06 Aug 2020 16:29:01

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:45', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5a1660b3-9112-4d4a-9baa-ee8edb66b7a3'	System	06 Aug 2020 16:29:01
User entered 'None (0)'	System	06 Aug 2020 16:29:01

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:46', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5a1660b3-9112-4d4a-9baa-ee8edb66b7a3'	System	06 Aug 2020 16:29:01
User entered 'None (0)'	System	06 Aug 2020 16:29:01

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:49', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5a1660b3-9112-4d4a-9baa-ee8edb66b7a3'	System	06 Aug 2020 16:29:01
User entered 'None (0)'	System	06 Aug 2020 16:29:01

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:50', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5a1660b3-9112-4d4a-9baa-ee8edb66b7a3'	System	06 Aug 2020 16:29:01
User entered 'None (0)'	System	06 Aug 2020 16:29:01

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:52', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5a1660b3-9112-4d4a-9baa-ee8edb66b7a3'	System	06 Aug 2020 16:29:01
User entered 'None (0)'	System	06 Aug 2020 16:29:01

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-06T12:28:54', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5a1660b3-9112-4d4a-9baa-ee8edb66b7a3'	System	06 Aug 2020 16:29:01
User entered 'No (N)'	System	06 Aug 2020 16:29:01

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:56', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5a1660b3-9112-4d4a-9baa-ee8edb66b7a3'	System	06 Aug 2020 16:29:01
User entered '06 Aug 2020 12:28'	System	06 Aug 2020 16:29:01

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 7'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:45', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'fa432eb8-1ca5-4295-8722-703f0bd9096f'	System	07 Aug 2020 17:03:01
User entered 'None (0)'	System	07 Aug 2020 17:03:01

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:47', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'fa432eb8-1ca5-4295-8722-703f0bd9096f'	System	07 Aug 2020 17:03:01
User entered 'None (0)'	System	07 Aug 2020 17:03:01

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:49', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'fa432eb8-1ca5-4295-8722-703f0bd9096f'	System	07 Aug 2020 17:03:01
User entered 'None (0)'	System	07 Aug 2020 17:03:01

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:50', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'fa432eb8-1ca5-4295-8722-703f0bd9096f' User entered 'None (0)'	System	07 Aug 2020 17:03:01

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:52', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'fa432eb8-1ca5-4295-8722-703f0bd9096f'	System	07 Aug 2020 17:03:01
User entered 'None (0)'	System	07 Aug 2020 17:03:01

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:53', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'fa432eb8-1ca5-4295-8722-703f0bd9096f'	System	07 Aug 2020 17:03:01
User entered 'None (0)'	System	07 Aug 2020 17:03:01

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

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 (180d86fffc3798)', Time: '2020-08-07T13:02:56', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'fa432eb8-1ca5-4295-8722-703f0bd9096f'	System	07 Aug 2020 17:03:01
User entered 'No (N)'	System	07 Aug 2020 17:03:01

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:57', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'fa432eb8-1ca5-4295-8722-703f0bd9096f'	System	07 Aug 2020 17:03:01
User entered '07 Aug 2020 13:02'	System	07 Aug 2020 17:03:01

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 14:29:27

US3402139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 12:38:25

US3402139

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:30:58
User entered '8 Aug 2020'	Traci Hull (b) (4)	10 Aug 2020 12:38:25

US3402139

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 12:38:25

US3402139

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Aug 2020 12:38:25

US3402139

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Aug 2020 12:38:31

US3402139

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 12:38:31

US3402139

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:37:08

US3402139

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:37:08

US3402139

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[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)	24 Aug 2020 21:37:08

US3402139

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:37:08

US3402139

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:37:14

US3402139

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 21:37:14

US3402139

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:37:29

US3402139

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:37:29

US3402139

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[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)	24 Aug 2020 21:37:29

US3402139

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:37:29

US3402139

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:37:37

US3402139

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 21:37:37

US3402139

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:34:26

US3402139

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:34:26

US3402139

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

[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)	31 Aug 2020 13:34:26

US3402139

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	31 Aug 2020 13:34:26

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '08:14'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 08:14'	System	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '63'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '14'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '114'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '60'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '09:12'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 09:12'	System	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '56'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '14'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '118'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '78'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Aug 2020 13:35:48

US3402139

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:56

US3402139

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:35:56

US3402139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	31 Aug 2020 12:56:03

US3402139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Abigail Wine (b) (4) (b) (4)	31 Aug 2020 12:56:03

US3402139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

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)	31 Aug 2020 12:56:03

US3402139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 12:56:03

US3402139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Abigail Wine (b) (4) (b) (4)	31 Aug 2020 12:56:03

US3402139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '08:40'	Abigail Wine (b) (4) (b) (4)	31 Aug 2020 12:56:03

US3402139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 08:40'	System	31 Aug 2020 12:56:03

US3402139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Abigail Wine (b) (4) (b) (4)	31 Aug 2020 12:56:03

US3402139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	31 Aug 2020 12:56:03

US3402139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 12:56:03

US3402139

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:36:10

US3402139

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:36:10

US3402139

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '08:33'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:36:10

US3402139

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 08:33'	System	31 Aug 2020 13:36:10

US3402139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:36:22

US3402139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:58

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:36:22

US3402139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:36:22

US3402139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '08:35'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:36:22

US3402139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '31 Aug 2020 08:35'	System	31 Aug 2020 13:36:22

US3402139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:58

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:36:22

US3402139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:36:22

US3402139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:36:22

US3402139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 13:36:22

US3402139

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 13:36:27

US3402139

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 13:36:27

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:10:45', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'cf875289-ec06-4636-b8c0-44bfa9779f74'	System	31 Aug 2020 13:11:19
User entered 'Yes (Y)'	System	31 Aug 2020 13:11:19

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:11:04', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'cf875289-ec06-4636-b8c0-44bfa9779f74'	System	31 Aug 2020 13:11:19
User entered '98.2'	System	31 Aug 2020 13:11:19

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:11:08', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'cf875289-ec06-4636-b8c0-44bfa9779f74'	System	31 Aug 2020 13:11:19
User entered 'No (N)'	System	31 Aug 2020 13:11:19

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86fffc3798)', Time: '2020-08-31T09:11:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'cf875289-ec06-4636-b8c0-44bfa9779f74'	System	31 Aug 2020 13:11:19
User entered '31 Aug 2020 09:11'	System	31 Aug 2020 13:11:19

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 09:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:30'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:25:38', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '591a24d4-0b88-4d3e-a3b2-496042749d48'	System	31 Aug 2020 17:27:20
User entered 'Yes (Y)'	System	31 Aug 2020 17:27:20

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:25:43', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '591a24d4-0b88-4d3e-a3b2-496042749d48'	System	31 Aug 2020 17:27:20
User entered '97.9'	System	31 Aug 2020 17:27:20

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:25:46', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '591a24d4-0b88-4d3e-a3b2-496042749d48'	System	31 Aug 2020 17:27:20
User entered 'No (N)'	System	31 Aug 2020 17:27:20

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:25:48', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '591a24d4-0b88-4d3e-a3b2-496042749d48'	System	31 Aug 2020 17:27:20
User entered '31 Aug 2020 13:25'	System	31 Aug 2020 17:27:20

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:25'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 2'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:11:36', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '893b4f5b-0c37-407c-bf97-cda312fa30d2'	System	01 Sep 2020 20:11:58
User entered 'Yes (Y)'	System	01 Sep 2020 20:11:58

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:11:43', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '893b4f5b-0c37-407c-bf97-cda312fa30d2'	System	01 Sep 2020 20:11:58
User entered '99.2'	System	01 Sep 2020 20:11:58

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:11:47', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '893b4f5b-0c37-407c-bf97-cda312fa30d2'	System	01 Sep 2020 20:11:58
User entered 'Yes (Y)'	System	01 Sep 2020 20:11:58

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed added to con med ' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 09:48:56
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:11:54', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '893b4f5b-0c37-407c-bf97-cda312fa30d2'	Tarin Gordon (b) (4)	08 Sep 2020 15:08:45
User entered '1'	System	01 Sep 2020 20:11:58
	System	01 Sep 2020 20:11:58
	System	01 Sep 2020 20:11:58

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:11:54', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '893b4f5b-0c37-407c-bf97-cda312fa30d2'	System	01 Sep 2020 20:11:58
User entered '0'	System	01 Sep 2020 20:11:58

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:11:57', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '893b4f5b-0c37-407c-bf97-cda312fa30d2'	System	01 Sep 2020 20:11:58
User entered '01 Sep 2020 16:11'	System	01 Sep 2020 20:11:58

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 3'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:52:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '73dfe5da-7ba5-402f-817e-74d2660fddbf'	System	02 Sep 2020 17:52:26
User entered 'Yes (Y)'	System	02 Sep 2020 17:52:26

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:52:19', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '73dfe5da-7ba5-402f-817e-74d2660fddbf'	System	02 Sep 2020 17:52:26
User entered '98.7'	System	02 Sep 2020 17:52:26

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:52:22', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '73dfe5da-7ba5-402f-817e-74d2660fddbf'	System	02 Sep 2020 17:52:26
User entered 'No (N)'	System	02 Sep 2020 17:52:26

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:52:24', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '73dfe5da-7ba5-402f-817e-74d2660fddbf'	System	02 Sep 2020 17:52:26
User entered '02 Sep 2020 13:52'	System	02 Sep 2020 17:52:26

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 4'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:41:04', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b91ea3d7-081a-4230-ae70-7fd974171ac6'	System	03 Sep 2020 16:41:17
User entered 'Yes (Y)'	System	03 Sep 2020 16:41:17

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:41:08', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b91ea3d7-081a-4230-ae70-7fd974171ac6'	System	03 Sep 2020 16:41:17
User entered '98.4'	System	03 Sep 2020 16:41:17

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:41:11', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b91ea3d7-081a-4230-ae70-7fd974171ac6'	System	03 Sep 2020 16:41:17
User entered 'No (N)'	System	03 Sep 2020 16:41:17

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:41:13', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b91ea3d7-081a-4230-ae70-7fd974171ac6'	System	03 Sep 2020 16:41:17
User entered '03 Sep 2020 12:41'	System	03 Sep 2020 16:41:17

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 5'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:46', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f1f3669f-658a-45c5-a802-1009608e5b32'	System	04 Sep 2020 16:04:48
User entered 'Yes (Y)'	System	04 Sep 2020 16:04:48

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:50', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f1f3669f-658a-45c5-a802-1009608e5b32'	System	04 Sep 2020 16:04:48
User entered '97.4'	System	04 Sep 2020 16:04:48

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:52', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f1f3669f-658a-45c5-a802-1009608e5b32'	System	04 Sep 2020 16:04:48
User entered 'No (N)'	System	04 Sep 2020 16:04:48

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:54', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f1f3669f-658a-45c5-a802-1009608e5b32'	System	04 Sep 2020 16:04:48
User entered '04 Sep 2020 12:02'	System	04 Sep 2020 16:04:48

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 6'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:03:52', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6d15294c-fec6-4ab8-8745-d70b00c62f71'	System	05 Sep 2020 16:05:08
User entered 'Yes (Y)'	System	05 Sep 2020 16:05:08

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:03:56', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6d15294c-fec6-4ab8-8745-d70b00c62f71'	System	05 Sep 2020 16:05:08
User entered '97.1'	System	05 Sep 2020 16:05:08

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6d15294c-fec6-4ab8-8745-d70b00c62f71'	System	05 Sep 2020 16:05:08
User entered 'No (N)'	System	05 Sep 2020 16:05:08

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:04', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6d15294c-fec6-4ab8-8745-d70b00c62f71'	System	05 Sep 2020 16:05:08
User entered '05 Sep 2020 12:04'	System	05 Sep 2020 16:05:08

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 7'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:41:25', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '157c0a52-8cff-450a-9c2d-7e07440c409f'	System	07 Sep 2020 00:41:49
User entered 'Yes (Y)'	System	07 Sep 2020 00:41:49

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:41:37', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '157c0a52-8cff-450a-9c2d-7e07440c409f'	System	07 Sep 2020 00:41:49
User entered '97.3'	System	07 Sep 2020 00:41:49

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:41:40', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '157c0a52-8cff-450a-9c2d-7e07440c409f'	System	07 Sep 2020 00:41:49
User entered 'No (N)'	System	07 Sep 2020 00:41:49

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:41:42', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '157c0a52-8cff-450a-9c2d-7e07440c409f'	System	07 Sep 2020 00:41:49
User entered '06 Sep 2020 20:41'	System	07 Sep 2020 00:41:49

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-31T09:11:39', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '33dbe681-b3e8-4515-8c8c-1ce97463743b'	System	31 Aug 2020 13:12:49
User entered 'None (1)'	System	31 Aug 2020 13:12:49

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:12:33', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '33dbe681-b3e8-4515-8c8c-1ce97463743b'	System	31 Aug 2020 13:12:49
User entered 'No (N)'	System	31 Aug 2020 13:12:49

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:12:36', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '33dbe681-b3e8-4515-8c8c-1ce97463743b'	System	31 Aug 2020 13:12:49
User entered 'No (N)'	System	31 Aug 2020 13:12:49

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-31T09:12:42', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '33dbe681-b3e8-4515-8c8c-1ce97463743b'	System	31 Aug 2020 13:12:49
User entered 'None (1)'	System	31 Aug 2020 13:12:49

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:12:45', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '33dbe681-b3e8-4515-8c8c-1ce97463743b'	System	31 Aug 2020 13:12:49
User entered '31 Aug 2020 09:12'	System	31 Aug 2020 13:12:49

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 09:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:30'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-31T13:25:53', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a7e4c1a5-6741-4539-8659-b900e6a5ad6a'	System	31 Aug 2020 17:27:23
User entered 'None (1)'	System	31 Aug 2020 17:27:23

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:25:55', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a7e4c1a5-6741-4539-8659-b900e6a5ad6a'	System	31 Aug 2020 17:27:23
User entered 'No (N)'	System	31 Aug 2020 17:27:23

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:25:58', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a7e4c1a5-6741-4539-8659-b900e6a5ad6a'	System	31 Aug 2020 17:27:23
User entered 'No (N)'	System	31 Aug 2020 17:27:23

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-31T13:26:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a7e4c1a5-6741-4539-8659-b900e6a5ad6a'	System	31 Aug 2020 17:27:23
User entered 'None (1)'	System	31 Aug 2020 17:27:23

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:26:04', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a7e4c1a5-6741-4539-8659-b900e6a5ad6a'	System	31 Aug 2020 17:27:23
User entered '31 Aug 2020 13:26'	System	31 Aug 2020 17:27:23

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:25'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 2'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-09-01T16:12:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6a1c103e-ade0-459c-8246-162a1d85f5b7'	System	01 Sep 2020 20:13:12
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	01 Sep 2020 20:13:12

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:12:41', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6a1c103e-ade0-459c-8246-162a1d85f5b7'	System	01 Sep 2020 20:13:12
User entered 'No (N)'	System	01 Sep 2020 20:13:12

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:12:53', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6a1c103e-ade0-459c-8246-162a1d85f5b7'	System	01 Sep 2020 20:13:12
User entered 'No (N)'	System	01 Sep 2020 20:13:12

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-09-01T16:13:07', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6a1c103e-ade0-459c-8246-162a1d85f5b7'	System	01 Sep 2020 20:13:12
User entered 'None (1)'	System	01 Sep 2020 20:13:12

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:13:12', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6a1c103e-ade0-459c-8246-162a1d85f5b7'	System	01 Sep 2020 20:13:12
User entered '01 Sep 2020 16:13'	System	01 Sep 2020 20:13:12

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 3'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-09-02T13:50:27', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5f76fd72-8c05-4af6-a662-d812854c319e'	System	02 Sep 2020 17:50:41
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 17:50:41

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:29', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5f76fd72-8c05-4af6-a662-d812854c319e'	System	02 Sep 2020 17:50:41
User entered 'No (N)'	System	02 Sep 2020 17:50:41

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:32', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5f76fd72-8c05-4af6-a662-d812854c319e'	System	02 Sep 2020 17:50:41
User entered 'No (N)'	System	02 Sep 2020 17:50:41

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-09-02T13:50:37', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5f76fd72-8c05-4af6-a662-d812854c319e'	System	02 Sep 2020 17:50:41
User entered 'None (1)'	System	02 Sep 2020 17:50:41

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:39', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5f76fd72-8c05-4af6-a662-d812854c319e'	System	02 Sep 2020 17:50:41
User entered '02 Sep 2020 13:50'	System	02 Sep 2020 17:50:41

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 4'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:58

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 (f0935be7a2d5bf5d)', Time: '2020-09-03T12:39:45', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '24df77ef-d015-4333-ab85-3bf1e40dccf8'	System	03 Sep 2020 16:39:59
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 16:39:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:39:47', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '24df77ef-d015-4333-ab85-3bf1e40dccf8'	System	03 Sep 2020 16:39:59
User entered 'No (N)'	System	03 Sep 2020 16:39:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:39:50', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '24df77ef-d015-4333-ab85-3bf1e40dccf8'	System	03 Sep 2020 16:39:59
User entered 'No (N)'	System	03 Sep 2020 16:39:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:58

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 (f0935be7a2d5bf5d)', Time: '2020-09-03T12:39:52', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '24df77ef-d015-4333-ab85-3bf1e40dccf8'	System	03 Sep 2020 16:39:59
User entered 'None (1)'	System	03 Sep 2020 16:39:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:39:54', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '24df77ef-d015-4333-ab85-3bf1e40dccf8'	System	03 Sep 2020 16:39:59
User entered '03 Sep 2020 12:39'	System	03 Sep 2020 16:39:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 5'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:58

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 (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:28', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '96def872-91c7-4231-b98a-21bc9ca9a037'	System	04 Sep 2020 16:04:26
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 16:04:26

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:32', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '96def872-91c7-4231-b98a-21bc9ca9a037'	System	04 Sep 2020 16:04:26
User entered 'No (N)'	System	04 Sep 2020 16:04:26

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:34', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '96def872-91c7-4231-b98a-21bc9ca9a037'	System	04 Sep 2020 16:04:26
User entered 'No (N)'	System	04 Sep 2020 16:04:26

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:58

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 (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:38', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '96def872-91c7-4231-b98a-21bc9ca9a037'	System	04 Sep 2020 16:04:26
User entered 'None (1)'	System	04 Sep 2020 16:04:26

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:40', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '96def872-91c7-4231-b98a-21bc9ca9a037'	System	04 Sep 2020 16:04:26
User entered '04 Sep 2020 12:02'	System	04 Sep 2020 16:04:26

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 6'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:58

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 (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:11', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '60dbba51-bb9f-4333-8e19-acf62a009027'	System	05 Sep 2020 16:05:19
User entered 'None (1)'	System	05 Sep 2020 16:05:19

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:14', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '60dbba51-bb9f-4333-8e19-acf62a009027'	System	05 Sep 2020 16:05:19
User entered 'No (N)'	System	05 Sep 2020 16:05:19

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:17', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '60dbba51-bb9f-4333-8e19-acf62a009027'	System	05 Sep 2020 16:05:19
User entered 'No (N)'	System	05 Sep 2020 16:05:19

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:58

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 (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:21', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '60dbba51-bb9f-4333-8e19-acf62a009027'	System	05 Sep 2020 16:05:19
User entered 'None (1)'	System	05 Sep 2020 16:05:19

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:23', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '60dbba51-bb9f-4333-8e19-acf62a009027'	System	05 Sep 2020 16:05:19
User entered '05 Sep 2020 12:04'	System	05 Sep 2020 16:05:19

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 7'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:58

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 (f0935be7a2d5bf5d)', Time: '2020-09-06T20:41:47', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8ce7960f-3867-4315-a24d-0baecd8b06ab'	System	07 Sep 2020 00:41:59
User entered 'None (1)'	System	07 Sep 2020 00:41:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:41:49', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8ce7960f-3867-4315-a24d-0baecd8b06ab'	System	07 Sep 2020 00:41:59
User entered 'No (N)'	System	07 Sep 2020 00:41:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:41:52', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8ce7960f-3867-4315-a24d-0baecd8b06ab'	System	07 Sep 2020 00:41:59
User entered 'No (N)'	System	07 Sep 2020 00:41:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:58

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 (f0935be7a2d5bf5d)', Time: '2020-09-06T20:41:54', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8ce7960f-3867-4315-a24d-0baecd8b06ab'	System	07 Sep 2020 00:41:59
User entered 'None (1)'	System	07 Sep 2020 00:41:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:41:57', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8ce7960f-3867-4315-a24d-0baecd8b06ab'	System	07 Sep 2020 00:41:59
User entered '06 Sep 2020 20:41'	System	07 Sep 2020 00:41:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:12:49', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '90e96343-aa5c-4d06-97c8-65cb18285e77'	System	31 Aug 2020 13:13:17
User entered 'None (0)'	System	31 Aug 2020 13:13:17

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:12:52', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '90e96343-aa5c-4d06-97c8-65cb18285e77'	System	31 Aug 2020 13:13:17
User entered 'None (0)'	System	31 Aug 2020 13:13:17

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:12:54', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '90e96343-aa5c-4d06-97c8-65cb18285e77'	System	31 Aug 2020 13:13:17
User entered 'None (0)'	System	31 Aug 2020 13:13:17

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:12:57', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '90e96343-aa5c-4d06-97c8-65cb18285e77'	System	31 Aug 2020 13:13:17
User entered 'None (0)'	System	31 Aug 2020 13:13:17

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:13:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '90e96343-aa5c-4d06-97c8-65cb18285e77'	System	31 Aug 2020 13:13:17
User entered 'None (0)'	System	31 Aug 2020 13:13:17

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:13:03', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '90e96343-aa5c-4d06-97c8-65cb18285e77'	System	31 Aug 2020 13:13:17
User entered 'None (0)'	System	31 Aug 2020 13:13:17

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-31T09:13:08', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '90e96343-aa5c-4d06-97c8-65cb18285e77'	System	31 Aug 2020 13:13:17
User entered 'No (N)'	System	31 Aug 2020 13:13:17

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:13:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '90e96343-aa5c-4d06-97c8-65cb18285e77'	System	31 Aug 2020 13:13:17
User entered '31 Aug 2020 09:13'	System	31 Aug 2020 13:13:17

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 09:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:30'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:26:08', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bef6547c-cad2-433b-ba02-199329348a36'	System	31 Aug 2020 17:27:40
User entered 'None (0)'	System	31 Aug 2020 17:27:40

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:26:10', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bef6547c-cad2-433b-ba02-199329348a36'	System	31 Aug 2020 17:27:40
User entered 'None (0)'	System	31 Aug 2020 17:27:40

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:26:11', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bef6547c-cad2-433b-ba02-199329348a36'	System	31 Aug 2020 17:27:40
User entered 'None (0)'	System	31 Aug 2020 17:27:40

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:26:13', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bef6547c-cad2-433b-ba02-199329348a36'	System	31 Aug 2020 17:27:40
User entered 'None (0)'	System	31 Aug 2020 17:27:40

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:26:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bef6547c-cad2-433b-ba02-199329348a36'	System	31 Aug 2020 17:27:40
User entered 'None (0)'	System	31 Aug 2020 17:27:40

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:26:17', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bef6547c-cad2-433b-ba02-199329348a36'	System	31 Aug 2020 17:27:40
User entered 'None (0)'	System	31 Aug 2020 17:27:40

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-08-31T13:26:21', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bef6547c-cad2-433b-ba02-199329348a36'	System	31 Aug 2020 17:27:40
User entered 'No (N)'	System	31 Aug 2020 17:27:40

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:26:23', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bef6547c-cad2-433b-ba02-199329348a36'	System	31 Aug 2020 17:27:40
User entered '31 Aug 2020 13:26'	System	31 Aug 2020 17:27:40

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:25'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 2'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:13:19', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '11cc5cd0-fa87-4705-bfe1-78d9733f6c1b'	System	01 Sep 2020 20:13:44
User entered 'None (0)'	System	01 Sep 2020 20:13:44

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:13:23', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '11cc5cd0-fa87-4705-bfe1-78d9733f6c1b'	System	01 Sep 2020 20:13:44
User entered 'No interference with activity (1)'	System	01 Sep 2020 20:13:44

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:13:30', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '11cc5cd0-fa87-4705-bfe1-78d9733f6c1b'	System	01 Sep 2020 20:13:44
User entered 'No interference with activity (1)'	System	01 Sep 2020 20:13:44

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:13:33', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '11cc5cd0-fa87-4705-bfe1-78d9733f6c1b'	System	01 Sep 2020 20:13:44
User entered 'None (0)'	System	01 Sep 2020 20:13:44

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:13:35', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '11cc5cd0-fa87-4705-bfe1-78d9733f6c1b'	System	01 Sep 2020 20:13:44
User entered 'None (0)'	System	01 Sep 2020 20:13:44

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:13:38', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '11cc5cd0-fa87-4705-bfe1-78d9733f6c1b'	System	01 Sep 2020 20:13:44
User entered 'None (0)'	System	01 Sep 2020 20:13:44

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

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 (180d86ffcec3798)', Time: '2020-09-01T16:13:41', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '11cc5cd0-fa87-4705-bfe1-78d9733f6c1b'	System	01 Sep 2020 20:13:44
User entered 'No (N)'	System	01 Sep 2020 20:13:44

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:13:44', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '11cc5cd0-fa87-4705-bfe1-78d9733f6c1b'	System	01 Sep 2020 20:13:44
User entered '01 Sep 2020 16:13'	System	01 Sep 2020 20:13:44

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 3'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:49:56', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '397bce19-fcf3-4e91-b167-bc6dddd455b0'	System	02 Sep 2020 17:50:21
User entered 'None (0)'	System	02 Sep 2020 17:50:21

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:01', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '397bce19-fcf3-4e91-b167-bc6dddd455b0'	System	02 Sep 2020 17:50:21
User entered 'None (0)'	System	02 Sep 2020 17:50:21

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:04', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '397bce19-fcf3-4e91-b167-bc6dddd455b0'	System	02 Sep 2020 17:50:21
User entered 'None (0)'	System	02 Sep 2020 17:50:21

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:08', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '397bce19-fcf3-4e91-b167-bc6dddd455b0'	System	02 Sep 2020 17:50:21
User entered 'None (0)'	System	02 Sep 2020 17:50:21

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:10', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '397bce19-fcf3-4e91-b167-bc6dddd455b0'	System	02 Sep 2020 17:50:21
User entered 'None (0)'	System	02 Sep 2020 17:50:21

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:12', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '397bce19-fcf3-4e91-b167-bc6dddd455b0'	System	02 Sep 2020 17:50:21
User entered 'None (0)'	System	02 Sep 2020 17:50:21

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

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 (180d86fffc3798)', Time: '2020-09-02T13:50:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '397bce19-fcf3-4e91-b167-bc6ddddd455b0'	System	02 Sep 2020 17:50:21
User entered 'No (N)'	System	02 Sep 2020 17:50:21

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:17', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '397bce19-fcf3-4e91-b167-bc6ddddd455b0'	System	02 Sep 2020 17:50:21
User entered '02 Sep 2020 13:50'	System	02 Sep 2020 17:50:21

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 4'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:40:09', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bd6a9c9d-5eef-4b44-b6e5-5758f9fb0482'	System	03 Sep 2020 16:40:27
User entered 'None (0)'	System	03 Sep 2020 16:40:27

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:40:11', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bd6a9c9d-5eef-4b44-b6e5-5758f9fb0482'	System	03 Sep 2020 16:40:27
User entered 'None (0)'	System	03 Sep 2020 16:40:27

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:40:13', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bd6a9c9d-5eef-4b44-b6e5-5758f9fb0482'	System	03 Sep 2020 16:40:27
User entered 'None (0)'	System	03 Sep 2020 16:40:27

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:40:14', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bd6a9c9d-5eef-4b44-b6e5-5758f9fb0482'	System	03 Sep 2020 16:40:27
User entered 'None (0)'	System	03 Sep 2020 16:40:27

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:40:16', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bd6a9c9d-5eef-4b44-b6e5-5758f9fb0482'	System	03 Sep 2020 16:40:27
User entered 'None (0)'	System	03 Sep 2020 16:40:27

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:40:18', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bd6a9c9d-5eef-4b44-b6e5-5758f9fb0482'	System	03 Sep 2020 16:40:27
User entered 'None (0)'	System	03 Sep 2020 16:40:27

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

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 (f0935be7a2d5bf5d)', Time: '2020-09-03T12:40:20', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bd6a9c9d-5eef-4b44-b6e5-5758f9fb0482'	System	03 Sep 2020 16:40:27
User entered 'No (N)'	System	03 Sep 2020 16:40:27

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:40:23', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bd6a9c9d-5eef-4b44-b6e5-5758f9fb0482'	System	03 Sep 2020 16:40:27
User entered '03 Sep 2020 12:40'	System	03 Sep 2020 16:40:27

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 5'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:01:55', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'eefc1b6f-d3f8-43cc-919b-900456325886'	System	04 Sep 2020 16:03:52
User entered 'None (0)'	System	04 Sep 2020 16:03:52

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:01:57', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'eefc1b6f-d3f8-43cc-919b-900456325886'	System	04 Sep 2020 16:03:52
User entered 'None (0)'	System	04 Sep 2020 16:03:52

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:01:59', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'eefc1b6f-d3f8-43cc-919b-900456325886'	System	04 Sep 2020 16:03:52
User entered 'None (0)'	System	04 Sep 2020 16:03:52

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:01', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'eefc1b6f-d3f8-43cc-919b-900456325886'	System	04 Sep 2020 16:03:52
User entered 'None (0)'	System	04 Sep 2020 16:03:52

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:03', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'eefc1b6f-d3f8-43cc-919b-900456325886'	System	04 Sep 2020 16:03:52
User entered 'None (0)'	System	04 Sep 2020 16:03:52

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:05', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'eefc1b6f-d3f8-43cc-919b-900456325886'	System	04 Sep 2020 16:03:52
User entered 'None (0)'	System	04 Sep 2020 16:03:52

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

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 (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:09', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'eefc1b6f-d3f8-43cc-919b-900456325886'	System	04 Sep 2020 16:03:52
User entered 'No (N)'	System	04 Sep 2020 16:03:52

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:11', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'eefc1b6f-d3f8-43cc-919b-900456325886'	System	04 Sep 2020 16:03:52
User entered '04 Sep 2020 12:02'	System	04 Sep 2020 16:03:52

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 6'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:27', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '161682c6-9f53-4bd3-b980-5e5c983f8be9'	System	05 Sep 2020 16:05:53
User entered 'None (0)'	System	05 Sep 2020 16:05:53

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:28', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '161682c6-9f53-4bd3-b980-5e5c983f8be9'	System	05 Sep 2020 16:05:53
User entered 'None (0)'	System	05 Sep 2020 16:05:53

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:30', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '161682c6-9f53-4bd3-b980-5e5c983f8be9'	System	05 Sep 2020 16:05:53
User entered 'None (0)'	System	05 Sep 2020 16:05:53

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:34', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '161682c6-9f53-4bd3-b980-5e5c983f8be9'	System	05 Sep 2020 16:05:53
User entered 'None (0)'	System	05 Sep 2020 16:05:53

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:38', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '161682c6-9f53-4bd3-b980-5e5c983f8be9'	System	05 Sep 2020 16:05:53
User entered 'None (0)'	System	05 Sep 2020 16:05:53

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:40', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '161682c6-9f53-4bd3-b980-5e5c983f8be9'	System	05 Sep 2020 16:05:53
User entered 'None (0)'	System	05 Sep 2020 16:05:53

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

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 (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:43', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '161682c6-9f53-4bd3-b980-5e5c983f8be9'	System	05 Sep 2020 16:05:53
User entered 'No (N)'	System	05 Sep 2020 16:05:53

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:47', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '161682c6-9f53-4bd3-b980-5e5c983f8be9'	System	05 Sep 2020 16:05:53
User entered '05 Sep 2020 12:04'	System	05 Sep 2020 16:05:53

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 12:56:03
User entered 'Day 7'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:42:01', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'ee8cd810-f937-496f-a736-9d53351ce2f0'	System	07 Sep 2020 00:42:26
User entered 'None (0)'	System	07 Sep 2020 00:42:26

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:42:03', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'ee8cd810-f937-496f-a736-9d53351ce2f0'	System	07 Sep 2020 00:42:26
User entered 'None (0)'	System	07 Sep 2020 00:42:26

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:42:05', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'ee8cd810-f937-496f-a736-9d53351ce2f0'	System	07 Sep 2020 00:42:26
User entered 'None (0)'	System	07 Sep 2020 00:42:26

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:42:09', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'ee8cd810-f937-496f-a736-9d53351ce2f0'	System	07 Sep 2020 00:42:26
User entered 'None (0)'	System	07 Sep 2020 00:42:26

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:42:12', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'ee8cd810-f937-496f-a736-9d53351ce2f0'	System	07 Sep 2020 00:42:26
User entered 'None (0)'	System	07 Sep 2020 00:42:26

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:42:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'ee8cd810-f937-496f-a736-9d53351ce2f0'	System	07 Sep 2020 00:42:26
User entered 'None (0)'	System	07 Sep 2020 00:42:26

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

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 (f0935be7a2d5bf5d)', Time: '2020-09-06T20:42:18', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'ee8cd810-f937-496f-a736-9d53351ce2f0'	System	07 Sep 2020 00:42:26
User entered 'No (N)'	System	07 Sep 2020 00:42:26

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:42:20', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'ee8cd810-f937-496f-a736-9d53351ce2f0'	System	07 Sep 2020 00:42:26
User entered '06 Sep 2020 20:42'	System	07 Sep 2020 00:42:26

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 12:56:03

US3402139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 12:56:03

US3402139

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 13:59:01

US3402139

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '08 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:32:10
User entered '8 Sep 2020'	Traci Hull (b) (4)	14 Sep 2020 13:59:01

US3402139

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[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)	14 Sep 2020 13:59:01

US3402139

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Sep 2020 13:59:01

US3402139

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 13:58:48

US3402139

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 13:58:48

US3402139

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	15 Sep 2020 11:30:22

US3402139

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Traci Hull (b) (4) (b) (4)	15 Sep 2020 11:30:22

US3402139

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[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 11:30:22

US3402139

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	15 Sep 2020 11:30:22

US3402139

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

[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 11:30:26

US3402139

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 11:30:26

US3402139

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	22 Sep 2020 11:50:12

US3402139

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Traci Hull (b) (4) (b) (4)	22 Sep 2020 11:50:12

US3402139

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[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)	22 Sep 2020 11:50:12

US3402139

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	22 Sep 2020 11:50:12

US3402139

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	22 Sep 2020 11:50:16

US3402139

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 11:50:16

US3402139

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	25 Sep 2020 17:23:07

US3402139

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Traci Hull (b) (4) (b) (4)	25 Sep 2020 17:23:07

US3402139

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

[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 Sep 2020 17:23:07

US3402139

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:58

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	25 Sep 2020 17:23:07

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	25 Sep 2020 17:24:03

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Traci Hull (b) (4) (b) (4)	25 Sep 2020 17:24:03

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '13:07'	Traci Hull (b) (4) (b) (4)	25 Sep 2020 17:24:03

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '25 Sep 2020 13:07'	System	25 Sep 2020 17:24:03

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.8' F	Traci Hull (b) (4) (b) (4)	25 Sep 2020 17:24:03

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	25 Sep 2020 17:24:03

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	25 Sep 2020 17:24:03

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '65'	Traci Hull (b) (4) (b) (4)	25 Sep 2020 17:24:03

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Sep 2020 17:24:03

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '12'	Traci Hull (b) (4) (b) (4)	25 Sep 2020 17:24:03

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Sep 2020 17:24:03

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '120'	Traci Hull (b) (4) (b) (4)	25 Sep 2020 17:24:03

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 17:24:03

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '73'	Traci Hull (b) (4) (b) (4)	25 Sep 2020 17:24:03

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Sep 2020 17:24:03

US3402139

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	25 Sep 2020 17:24:27

US3402139

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	25 Sep 2020 17:24:27

US3402139

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	25 Sep 2020 17:24:39

US3402139

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Traci Hull (b) (4) (b) (4)	25 Sep 2020 17:24:39

US3402139

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:13'	Traci Hull (b) (4) (b) (4)	25 Sep 2020 17:24:39

US3402139

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '25 Sep 2020 13:13'	System	25 Sep 2020 17:24:39

US3402139

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	25 Sep 2020 17:24:44

US3402139

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 17:24:44

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 64'	System	01 Aug 2020 14:29:27

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[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 (f0935be7a2d5bf5d)', Time: '2020-10-02T10:50:22', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a648b738-bdc5-4c0d-806a-13767a7e9e20'	System	02 Oct 2020 14:50:50
User entered 'No (N)'	System	02 Oct 2020 14:50:50

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

Have you been exposed to someone with 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 (f0935be7a2d5bf5d)', Time: '2020-10-02T10:50:34', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a648b738-bdc5-4c0d-806a-13767a7e9e20'	System	02 Oct 2020 14:50:50
User entered 'No (N)'	System	02 Oct 2020 14:50:50

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-10-02T10:50:46', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a648b738-bdc5-4c0d-806a-13767a7e9e20'	System	02 Oct 2020 14:50:50
User entered '02 Oct 2020 10:50:46'	System	02 Oct 2020 14:50:50

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered '01 Oct 2020 00:01'	System	01 Aug 2020 14:29:27

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered '05 Oct 2020 23:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 71'	System	01 Aug 2020 14:29:27

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[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 (f0935be7a2d5bf5d)', Time: '2020-10-10T07:32:05', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4b6bb205-e0c7-4ff0-922d-ebd2bdcc34e'	System	10 Oct 2020 11:32:22
User entered 'No (N)'	System	10 Oct 2020 11:32:22

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

Have you been exposed to someone with 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 (f0935be7a2d5bf5d)', Time: '2020-10-10T07:32:12', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4b6bb205-e0c7-4ff0-922d-ebcd2bdcc34e'	System	10 Oct 2020 11:32:22
User entered 'No (N)'	System	10 Oct 2020 11:32:22

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-10-10T07:32:16', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4b6bb205-e0c7-4ff0-922d-ebcd2bdcc34e'	System	10 Oct 2020 11:32:22
User entered '10 Oct 2020 07:32:16'	System	10 Oct 2020 11:32:22

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered '08 Oct 2020 00:01'	System	01 Aug 2020 14:29:27

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered '12 Oct 2020 23:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 78'	System	01 Aug 2020 14:29:27

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[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 (f0935be7a2d5bf5d)', Time: '2020-10-18T07:47:51', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b2c6776f-9c1a-4037-bd13-ecddc8a77dc5'	System	18 Oct 2020 11:48:16
User entered 'No (N)'	System	18 Oct 2020 11:48:16

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

Have you been exposed to someone with 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 (f0935be7a2d5bf5d)', Time: '2020-10-18T07:47:56', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b2c6776f-9c1a-4037-bd13-ecddc8a77dc5'	System	18 Oct 2020 11:48:16
User entered 'No (N)'	System	18 Oct 2020 11:48:16

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-10-18T07:47:59', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b2c6776f-9c1a-4037-bd13-ecddc8a77dc5'	System	18 Oct 2020 11:48:16
User entered '18 Oct 2020 07:47:59'	System	18 Oct 2020 11:48:16

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered '15 Oct 2020 00:01'	System	01 Aug 2020 14:29:27

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered '19 Oct 2020 23:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 92'	System	01 Aug 2020 14:29:27

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[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 (f0935be7a2d5bf5d)', Time: '2020-10-30T10:04:04', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '2c74702c-9abb-46ba-af9e-43e2f466a92b'	System	30 Oct 2020 14:04:14
User entered 'No (N)'	System	30 Oct 2020 14:04:14

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

Have you been exposed to someone with 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 (f0935be7a2d5bf5d)', Time: '2020-10-30T10:04:08', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '2c74702c-9abb-46ba-af9e-43e2f466a92b'	System	30 Oct 2020 14:04:14
User entered 'No (N)'	System	30 Oct 2020 14:04:14

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-10-30T10:04:11', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '2c74702c-9abb-46ba-af9e-43e2f466a92b'	System	30 Oct 2020 14:04:14
User entered '30 Oct 2020 10:04:11'	System	30 Oct 2020 14:04:14

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered '29 Oct 2020 00:01'	System	01 Aug 2020 14:29:27

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered '02 Nov 2020 23:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 99'	System	01 Aug 2020 14:29:27

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 (f0935be7a2d5bf5d)', Time: '2020-11-07T07:42:55', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6cdf2592-0bb0-4afd-8d48-3996193d6d0e'	System	07 Nov 2020 12:43:20
User entered 'No (N)'	System	07 Nov 2020 12:43:20

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

Have you been exposed to someone with 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 (f0935be7a2d5bf5d)', Time: '2020-11-07T07:43:13', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6cdf2592-0bb0-4afd-8d48-3996193d6d0e'	System	07 Nov 2020 12:43:20
User entered 'No (N)'	System	07 Nov 2020 12:43:20

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-11-07T07:43:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6cdf2592-0bb0-4afd-8d48-3996193d6d0e'	System	07 Nov 2020 12:43:20
User entered '07 Nov 2020 07:43:15'	System	07 Nov 2020 12:43:20

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered '05 Nov 2020 00:01'	System	01 Aug 2020 14:29:27

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered '09 Nov 2020 23:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered 'Day 106'	System	01 Aug 2020 14:29:27

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

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 (f0935be7a2d5bf5d)', Time: '2020-11-16T16:53:03', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0a405e48-56f8-4d6c-a188-980aff92d114'	System	16 Nov 2020 21:53:17
User entered 'No (N)'	System	16 Nov 2020 21:53:17

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

Have you been exposed to someone with 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 (f0935be7a2d5bf5d)', Time: '2020-11-16T16:53:10', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0a405e48-56f8-4d6c-a188-980aff92d114'	System	16 Nov 2020 21:53:17
User entered 'No (N)'	System	16 Nov 2020 21:53:17

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-11-16T16:53:13', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0a405e48-56f8-4d6c-a188-980aff92d114'	System	16 Nov 2020 21:53:17
User entered '16 Nov 2020 16:53:13'	System	16 Nov 2020 21:53:17

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered '12 Nov 2020 00:01'	System	01 Aug 2020 14:29:27

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 14:29:27
User entered '16 Nov 2020 23:59'	System	01 Aug 2020 14:29:27

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '28 Sep 2020 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '02 Oct 2020 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '05 Oct 2020 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '09 Oct 2020 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '12 Oct 2020 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '16 Oct 2020 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '19 Oct 2020 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '23 Oct 2020 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '26 Oct 2020 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '30 Oct 2020 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '02 Nov 2020 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '06 Nov 2020 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '09 Nov 2020 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '13 Nov 2020 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[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 (a05f4ca97dbea170)', Time: '2020-11-19T16:50:51', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '413a93b5-d68c-4cc7-b34e-d785b628697e'	System	19 Nov 2020 21:51:04
User entered 'No (N)'	System	19 Nov 2020 21:51:04

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

Have you been exposed to someone with 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 (a05f4ca97dbea170)', Time: '2020-11-19T16:50:56', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '413a93b5-d68c-4cc7-b34e-d785b628697e'	System	19 Nov 2020 21:51:04
User entered 'No (N)'	System	19 Nov 2020 21:51:04

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2020-11-19T16:50:59', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '413a93b5-d68c-4cc7-b34e-d785b628697e' User entered '19 Nov 2020 16:50:59'	System	19 Nov 2020 21:51:04
	System	19 Nov 2020 21:51:04

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 11:17:15

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 11:17:15

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:17:15

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Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 11:17:15

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:17:15

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Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 11:17:15

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 11:17:15

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:17:15

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 11:17:15

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:17:15

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 11:17:15

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:17:15
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 11:17:15

US3402139

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:23:58

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:58:18
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4)	26 Oct 2020 19:21:51
User entered 'No (N)'	Traci Hull (b) (4)	03 Sep 2020 19:42:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:58

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:39:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:47:34
User entered	System	27 Oct 2020 14:19:05
'USA-US059-2020-mRNA-1273-P301000014'		
User entered 'New'	(b) (4), (b) (6)	27 Oct 2020 14:19:05

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:47:32
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 11:48:30
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 11:48:30
	(b) (4)	
Data point term sent to Coder	System	07 Nov 2020 13:19:32
Coding entries removed.	Jennifer Molstead (b) (4)	07 Nov 2020 13:18:37
	(b) (4)	
User entered 'WORSENING LEFT KNEE ARTHRITIS' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 13:18:37
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 19:47:07
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Oct 2020 19:47:07
	(b) (4)	
Data point term sent to Coder	System	26 Oct 2020 19:32:21
User entered 'Left Knee Arthritis'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:02:32
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:47:31
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:03:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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Folder: Adverse Events

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Generated On: 26 Nov 2020 09:23:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:47:28
User closed query 'PV Query: Currently, the start date of the event was reported as the day the subject was hospitalized to undergo a left knee replacement as surgical treatment for the event. Please consider updating the start date of the event to the date the subject first experienced signs and symptoms of the left knee arthritis.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 21:15:42
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Nov 2020 18:24:19
User entered '09 Aug 2020' reason for change: Per Query Resolution	Tammy Kohn (b) (4)	07 Nov 2020 18:24:19
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Nov 2020 13:25:20
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Nov 2020 13:25:20
User entered 'UN Aug 2020' (non-conformant).	Jennifer Molstead (b) (4)	07 Nov 2020 13:25:20
Query 'PV Query: Currently, the start date of the event was reported as the day the subject was hospitalized to undergo a left knee replacement as surgical treatment for the event. Please consider updating the start date of the event to the date the subject first experienced signs and symptoms of the left knee arthritis.' answered with 'UPDATED' (Site from Safety).	Jennifer Molstead (b) (4)	07 Nov 2020 13:18:51
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Nov 2020 13:18:37
User entered 'un Aug 2002' (non-conformant).	Jennifer Molstead (b) (4)	07 Nov 2020 13:18:37
User opened query 'PV Query: Currently, the start date of the event was reported as the day the subject was hospitalized to undergo a left knee replacement as surgical treatment for the event. Please consider updating the start date of the event to the date the subject first experienced signs and symptoms of the left knee arthritis.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 14:51:42
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:47:26
User entered empty.	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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Generated On: 26 Nov 2020 09:23:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 19:32:02

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:47:24
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:47:23
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:47:21
User entered empty.	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Oct 2020 19:32:02

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:47:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:47:11
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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Folder: Adverse Events

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:47:08
User entered '0'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:47:07
User entered '0'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:47:05
User entered '1'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:02:23
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:46:52
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:46:56
User entered 'No (N)'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:46:59
User entered empty.	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:47:00
User entered '0'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:47:01
User entered '0'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:47:03
User entered '0'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:46:22
User closed query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 21:16:18
Query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' answered with 'UPDATED' (Site from Safety).	Jennifer Molstead (b) (4)	07 Nov 2020 13:18:58
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 13:18:37
	(b) (4)	
User opened query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 14:51:21
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 03:09:14
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:46:24
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'NOT RELATED' (Site from DM).	Tammy Kohn (b) (4)	18 Nov 2020 14:19:36
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 14:19:29
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:03:31
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:46:29
User entered 'None (NONE)' reason for change: Per Query Resolution	Tammy Kohn (b) (4)	17 Nov 2020 21:24:59
User closed query 'PV Query: As the last dose of mRNA-1273 vs placebo was given on 31 Aug 2020, please update the action taken with mRNA-1273 vs placebo from none to not applicable. Please update the EDC accordingly.' (Site from Safety).	(b) (4)	
Query 'PV Query: As the last dose of mRNA-1273 vs placebo was given on 31 Aug 2020, please update the action taken with mRNA-1273 vs placebo from none to not applicable. Please update the EDC accordingly.' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 21:16:05
Query 'PV Query: As the last dose of mRNA-1273 vs placebo was given on 31 Aug 2020, please update the action taken with mRNA-1273 vs placebo from none to not applicable. Please update the EDC accordingly.' answered with 'UPDATED' (Site from Safety).	Jennifer Molstead (b) (4)	07 Nov 2020 13:19:04
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	(b) (4)	07 Nov 2020 13:18:37
User opened query 'PV Query: As the last dose of mRNA-1273 vs placebo was given on 31 Aug 2020, please update the action taken with mRNA-1273 vs placebo from none to not applicable. Please update the EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 14:49:25
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:32:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:32:57
User entered 'None (NONE)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:57
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	26 Oct 2020 19:32:02
	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:06:56
DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Nov 2020 16:02:48
	(b) (4)	
User entered '0' reason for change: Per Query Resolution	Tammy Kohn (b) (4)	23 Nov 2020 16:02:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:46:34
User closed query 'PV Query: As event start date was updated, please consider updating action taken from not applicable to none. ' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 14:44:53
Query 'PV Query: As event start date was updated, please consider updating action taken from not applicable to none. ' answered with 'data updated' (Site from Safety).	Tammy Kohn (b) (4)	17 Nov 2020 21:24:50
	(b) (4)	
User opened query 'PV Query: As event start date was updated, please consider updating action taken from not applicable to none. ' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 21:22:21
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	26 Oct 2020 19:32:57
User entered '1' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:57
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	26 Oct 2020 19:32:02
User entered '0'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Please check mark as per source - subject had medications in ConMed Log corresponding with this AE. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:52:19
	(b) (4), (b) (6)	23 Nov 2020 22:06:56
Query 'Please check mark as per source - subject had medications in ConMed Log corresponding with this AE. ' answered with 'data updated' (Site from CRA). DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Nov 2020 16:03:17
	Tammy Kohn (b) (4)	23 Nov 2020 16:02:48
User entered '1' reason for change: Data Entry Error	Tammy Kohn (b) (4)	23 Nov 2020 16:02:48
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:54:43
User opened query 'Please check mark as per source - subject had medications in ConMed Log corresponding with this AE. ' (Site from CRA). User entered '0'	(b) (4), (b) (6)	20 Nov 2020 19:54:12
	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Please check mark as per source - subject had surgery in Con Procedure Log corresponding with this AE. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:52:25
	(b) (4), (b) (6)	23 Nov 2020 22:06:56
Query 'Please check mark as per source - subject had surgery in Con Procedure Log corresponding with this AE. ' answered with 'data updated' (Site from CRA). DataPoint Un-verified.	Tammy Kohn (b) (4)	23 Nov 2020 16:03:24
	(b) (4)	23 Nov 2020 16:02:48
User entered '1' reason for change: Data Entry Error	Tammy Kohn (b) (4)	23 Nov 2020 16:02:48
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:54:41
User opened query 'Please check mark as per source - subject had surgery in Con Procedure Log corresponding with this AE. ' (Site from CRA). User entered '0'	(b) (4), (b) (6)	20 Nov 2020 19:54:40
	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:01:51
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:06:56
User entered 'Subject undergoing physical therapy'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 2. ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 13:39:46
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include dates, units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 13:39:45
User closed query 'PV Query: Please provide treatment given for the event including medical intervention. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 13:39:43
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)	24 Nov 2020 13:39:41
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:06:56
Query 'PV Query: Please provide treatment given for the event including medical intervention. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	23 Nov 2020 18:07:08
Query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 2. ' answered with 'correct as is' (Site from Safety).	Jennifer Molstead (b) (4)	23 Nov 2020 18:06:58
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include dates, units and reference ranges if applicable. ' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	23 Nov 2020 18:06:03
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 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	23 Nov 2020 18:05:31

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS ADMITTED 12OCT2020 FOR A LEFT KNEE REPLACEMENT. SUBJECT WAS DISCHARGED 14OCT2020. Subject did have covid 19 testing done which was negative. Subject did have complete blood count which showed that the hemaglobin was 10.8 on 13Nov2020, and 11.1 14Nov2020 both of which were low the normal range is 12.0-16.0.' reason for change: Per Query Resolution DataPoint Un-verified.	Jennifer Molstead (b) (4)	23 Nov 2020 18:05:19
	(b) (4), (b) (6)	20 Nov 2020 19:02:01
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 19:01:59
User opened query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 2.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 21:22:59
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include dates, units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 21:22:45
User opened query 'PV Query: Please provide treatment given for the event including medical intervention. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 21:22:33
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)	17 Nov 2020 21:21:49
User closed query 'PV Query: Please confirm left knee arthritis was not considered as medical history.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 21:16:51

US3402139

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:58

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 21:16:43
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include dates, units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 21:16:35
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)	09 Nov 2020 21:16:23
Query 'PV Query: Please confirm left knee arthritis was not considered as medical history.' answered with 'This is prior medical history. Will update' (Site from Safety).	Jennifer Molstead (b) (4)	07 Nov 2020 13:20:14
Query 'PV Query: Please provide treatment given for the event including medical intervention. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'SUBJECT HAS NOT YET ALLOWED MEDICAL RECORDS TO BE RELEASED' (Site from Safety).	Jennifer Molstead (b) (4)	07 Nov 2020 13:19:57
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include dates, units and reference ranges if applicable.' answered with 'SUBJECT HAS NOT YET ALLOWED MEDICAL RECORDS TO BE RELEASED' (Site from Safety).	Jennifer Molstead (b) (4)	07 Nov 2020 13:19:52
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 'UPDATED' (Site from Safety).	Jennifer Molstead (b) (4)	07 Nov 2020 13:19:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:58

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS ADMITTED 12OCT2020 FOR A LEFT KNEE REPLACEMENT. SUBJECT WAS DISCHARGED 14OCT2020. AWAITING MEDICAL RECORDS. AT THIS POINT NO MEDICAL RECORDS HAVE BEEN RECEIVED. CAN NOT DETERMIN IF ANY COVID TESTING WAS PERFORMED.' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 13:18:37
User opened query 'PV Query: Please confirm left knee arthritis was not considered as medical history.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 14:51:57
User opened query 'PV Query: Please provide treatment given for the event including medical intervention. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 14:50:26
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include dates, units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 14:50:13
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 14:49:44
User entered 'Subject was admitted 12Oct2020 for a left knee replacement. Subject was discharged 14Oct2020. Awaiting medical records.'	Jennifer Molstead (b) (4)	26 Oct 2020 19:32:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 19:32:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 19:32:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User entered '0'	System	26 Oct 2020 19:32:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
User closed query 'Per source - please verify and add the following to EDC ConMeds. - Hydrocodone/Acetaminophen - 5mg/325mg, PO, PRN for L. Knee Replacement - Start date 12 Oct 2020, ongoing, taken for solicited event - Yes. - Amoxicillin / Clavulanic Acid - 125mg/875mg, PO, QD L. Knee Replacement - Start date 12 Oct 2020, Stop date 22 Oct 2020, taken for solicited event - Yes.' (Site from CRA).	(b) (4), (b) (6) [REDACTED] [REDACTED]	24 Nov 2020 20:54:53
Query 'Per source - please verify and add the following to EDC ConMeds. - Hydrocodone/Acetaminophen - 5mg/325mg, PO, PRN for L. Knee Replacement - Start date 12 Oct 2020, ongoing, taken for solicited event - Yes. - Amoxicillin / Clavulanic Acid - 125mg/875mg, PO, QD L. Knee Replacement - Start date 12 Oct 2020, Stop date 22 Oct 2020, taken for solicited event - Yes.' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4) [REDACTED]	23 Nov 2020 19:47:58
User opened query 'Per source - please verify and add the following to EDC ConMeds. - Hydrocodone/Acetaminophen - 5mg/325mg, PO, PRN for L. Knee Replacement - Start date 12 Oct 2020, ongoing, taken for solicited event - Yes. - Amoxicillin / Clavulanic Acid - 125mg/875mg, PO, QD L. Knee Replacement - Start date 12 Oct 2020, Stop date 22 Oct 2020, taken for solicited event - Yes.' (Site from CRA).	(b) (4), (b) (6) [REDACTED] [REDACTED]	20 Nov 2020 19:45:17
DataPoint Verified.	(b) (4), (b) (6) [REDACTED] [REDACTED]	04 Nov 2020 21:18:42
User closed query 'Per ETRTR: Please confirm no medication has been dosed for SAE "Left Knee Arthritis". Update ConMeds and AE CRF otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6) [REDACTED] [REDACTED]	04 Nov 2020 21:18:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:23:58

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Query 'Per ETRTR: Please confirm no medication has been dosed for SAE "Left Knee Arthritis". Update ConMeds and AE CRF otherwise, thanks.' answered with 'LEFT KNEE REPLACEMENT IS AN AE ALREADY IN THE SYSTEM. CALLED SPOKE TO PATIENT STATED SHE HAS NOT TAKEN ANYTHING NEW FOR MEDICATIONS. ' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	30 Oct 2020 14:40:34
User opened query 'Per ETRTR: Please confirm no medication has been dosed for SAE "Left Knee Arthritis". Update ConMeds and AE CRF otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 20:51:54
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	01 Aug 2020 16:40:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 11:32:59
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 11:32:59
	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 16:51:49
User entered 'LEVOCETIRIZINE'	Tarin Gordon (b) (4)	01 Aug 2020 16:50:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Tarin Gordon (b) (4)	01 Aug 2020 16:50:54
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'ENVIRONMENTAL ALLERGIES'	Tarin Gordon (b) (4)	01 Aug 2020 16:50:54
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '5'	Tarin Gordon (b) (4)	01 Aug 2020 16:50:54
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'mg (mg)'	Tarin Gordon (b) (4)	01 Aug 2020 16:50:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Tarin Gordon (b) (4)	01 Aug 2020 16:50:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	01 Aug 2020 16:50:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Tarin Gordon (b) (4)	01 Aug 2020 16:50:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	01 Aug 2020 16:50:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Tarin Gordon (b) (4)	01 Aug 2020 16:50:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 20:06:02
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Tarin Gordon (b) (4)	01 Aug 2020 16:54:52
answered with 'ONGOING' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	01 Aug 2020 16:50:54
User entered 'UN May 2019'	Tarin Gordon (b) (4)	01 Aug 2020 16:50:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Tarin Gordon (b) (4)	01 Aug 2020 16:50:54
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	01 Aug 2020 16:50:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Tarin Gordon (b) (4)	01 Aug 2020 16:50:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Tarin Gordon (b) (4)	01 Aug 2020 16:50:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 16:50:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 16:50:54

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Aug 2020 16:50:54

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: RIZATRIPTAN BENZOATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 02:14:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 02:14:46
	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 16:52:49
User entered 'RIZATRIPTAN BENZOATE'	Tarin Gordon (b) (4)	01 Aug 2020 16:51:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Tarin Gordon (b) (4)	01 Aug 2020 16:51:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'MIGRAINE HEADACHES'	Tarin Gordon (b) (4)	01 Aug 2020 16:51:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '10'	Tarin Gordon (b) (4)	01 Aug 2020 16:51:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'mg (mg)'	Tarin Gordon (b) (4)	01 Aug 2020 16:51:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Tarin Gordon (b) (4)	01 Aug 2020 16:51:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'as needed (PRN)'	Tarin Gordon (b) (4)	01 Aug 2020 16:51:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Tarin Gordon (b) (4)	01 Aug 2020 16:51:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	01 Aug 2020 16:51:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Tarin Gordon (b) (4)	01 Aug 2020 16:51:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 20:06:07
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	01 Aug 2020 16:54:47
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	01 Aug 2020 16:51:59
User entered 'UN UNK 2007'	Tarin Gordon (b) (4)	01 Aug 2020 16:51:59

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Tarin Gordon (b) (4)	01 Aug 2020 16:51:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	01 Aug 2020 16:51:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Tarin Gordon (b) (4)	01 Aug 2020 16:51:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Tarin Gordon (b) (4)	01 Aug 2020 16:51:59
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:51:59

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:51:59

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:51:59

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Nov 2020 01:33:35
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Nov 2020 01:33:35
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA RHIZOME, PRODUCTSYNONYM: CURCUMIN TURMERIC - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Sep 2020 14:25:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Sep 2020 14:25:49
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 14:24:46
Coding entries removed.	Traci Hull (b) (4)	30 Sep 2020 14:24:37
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA RHIZOME, PRODUCTSYNONYM: CURCUMIN TURMERIC - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Aug 2020 16:05:10
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Aug 2020 16:05:10
	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 16:54:51
User entered 'TURMERIC CURCUMIN'	Tarin Gordon (b) (4)	01 Aug 2020 16:53:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	01 Aug 2020 16:53:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'NUTRITIONAL SUPPLEMENT'	Traci Hull (b) (4)	30 Sep 2020 14:24:37
reason for change: New Information	(b) (4)	
User entered 'SUPPLEMENT'	Tarin Gordon (b) (4)	01 Aug 2020 16:53:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '500'	Tarin Gordon (b) (4)	01 Aug 2020 16:53:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'mg (mg)'	Tarin Gordon (b) (4)	01 Aug 2020 16:53:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Tarin Gordon (b) (4)	01 Aug 2020 16:53:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'as needed (PRN)'	Tarin Gordon (b) (4)	01 Aug 2020 16:53:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Tarin Gordon (b) (4)	01 Aug 2020 16:53:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	01 Aug 2020 16:53:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Tarin Gordon (b) (4)	01 Aug 2020 16:53:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 20:06:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Tarin Gordon (b) (4)	01 Aug 2020 16:54:41
answered with 'ONGOING' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	01 Aug 2020 16:53:56
User entered 'UN Apr 2020'	Tarin Gordon (b) (4)	01 Aug 2020 16:53:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Tarin Gordon (b) (4)	01 Aug 2020 16:53:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	01 Aug 2020 16:53:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Tarin Gordon (b) (4)	01 Aug 2020 16:53:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Tarin Gordon (b) (4)	01 Aug 2020 16:53:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:53:56

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:53:56

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:53:56

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM OXIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Sep 2020 14:25:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Sep 2020 14:25:50
	(b) (4)	
Data point term sent to Coder Coding entries removed.	System	30 Sep 2020 14:24:44
	Traci Hull (b) (4)	30 Sep 2020 14:24:22
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM OXIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Aug 2020 13:06:59
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Aug 2020 13:06:59
	(b) (4)	
Data point term sent to Coder	System	01 Aug 2020 16:54:51
User entered 'MAGNESIUM OXIDE'	Tarin Gordon (b) (4)	01 Aug 2020 16:54:30
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	01 Aug 2020 16:54:30
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'NUTRITIONAL SUPPLEMENT'	Traci Hull (b) (4)	30 Sep 2020 14:24:22
reason for change: New Information	(b) (4)	
User entered 'SUPPLEMENT'	Tarin Gordon (b) (4)	01 Aug 2020 16:54:30
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '250'	Tarin Gordon (b) (4)	01 Aug 2020 16:54:30
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'mg (mg)'	Tarin Gordon (b) (4)	01 Aug 2020 16:54:30
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Tarin Gordon (b) (4)	01 Aug 2020 16:54:30
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'as needed (PRN)'	Tarin Gordon (b) (4)	01 Aug 2020 16:54:30
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Tarin Gordon (b) (4)	01 Aug 2020 16:54:30
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	01 Aug 2020 16:54:30
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Tarin Gordon (b) (4)	01 Aug 2020 16:54:30
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 20:06:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	01 Aug 2020 16:54:36
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	01 Aug 2020 16:54:30
User entered 'UN Apr 2020'	Tarin Gordon (b) (4)	01 Aug 2020 16:54:30

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Tarin Gordon (b) (4)	01 Aug 2020 16:54:30
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	01 Aug 2020 16:54:30
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Tarin Gordon (b) (4)	01 Aug 2020 16:54:30
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Tarin Gordon (b) (4)	01 Aug 2020 16:54:30
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:54:30

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:54:30

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:54:30

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 11:25:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 11:25:44
	(b) (4)	
Data point term sent to Coder	System	26 Oct 2020 11:24:41
Coding entries removed.	Tammy Kohn (b) (4)	26 Oct 2020 11:23:49
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 14:25:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 14:25:50
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 14:24:42
Coding entries removed.	Traci Hull (b) (4)	30 Sep 2020 14:24:03
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 15:10:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 15:10:46
	(b) (4)	
Data point term sent to Coder	System	08 Sep 2020 15:09:53
User entered 'ACETAMINOPHEN'	Tarin Gordon (b) (4)	08 Sep 2020 15:09:44
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	08 Sep 2020 15:09:44
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:34:03
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'PATIENT HAD MILD PAIN AT INJECTION SITE NO AE OR SAE ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	26 Oct 2020 11:24:10
User entered 'MILD PAIN AT INJECTION SITE ON DAY 2 OF DIARY AND BODY ACHES' reason for change: New Information	Tammy Kohn (b) (4) (b) (4)	26 Oct 2020 11:23:49
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 09:59:14
Query ' Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN ON DAY 2 OF DIARY is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN ON DAY 2 OF DIARY did not meet the AE reporting criteria.' canceled (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 11:12:27

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
User opened query ' Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN ON DAY 2 OF DIARY is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN ON DAY 2 OF DIARY did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 04:36:14
User entered 'PAIN ON DAY 2 OF DIARY AND BODY ACHES' reason for change: New Information	Traci Hull (b) (4)	30 Sep 2020 14:24:03
User entered 'PAIN ON DAY 2 OF DIARY'	Tarin Gordon (b) (4)	08 Sep 2020 15:09:44

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '1000'	Tarin Gordon (b) (4)	08 Sep 2020 15:09:44
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'mg (mg)'	Tarin Gordon (b) (4)	08 Sep 2020 15:09:44
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Tarin Gordon (b) (4)	08 Sep 2020 15:09:44
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'once (ONCE)'	Tarin Gordon (b) (4)	08 Sep 2020 15:09:44
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Tarin Gordon (b) (4)	08 Sep 2020 15:09:44
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	08 Sep 2020 15:09:44
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Tarin Gordon (b) (4)	08 Sep 2020 15:09:44
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '02 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:34:02
	(b) (4)	
User entered '2 Sep 2020'	Tarin Gordon (b) (4)	08 Sep 2020 15:09:44
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Tarin Gordon (b) (4)	08 Sep 2020 15:09:44
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Tarin Gordon (b) (4)	08 Sep 2020 15:09:44
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '02 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:34:02
	(b) (4)	
User entered '2 Sep 2020'	Tarin Gordon (b) (4)	08 Sep 2020 15:09:44
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:10:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 15:10:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Tarin Gordon (b) (4)	08 Sep 2020 15:10:54
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 15:09:44
User entered empty.	Tarin Gordon (b) (4)	08 Sep 2020 15:09:44
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 15:09:44

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 15:09:44

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 15:09:44

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 19:55:17
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 19:55:17
	(b) (4)	
Data point term sent to Coder	System	23 Nov 2020 18:19:27
User entered 'Ambien'	Jennifer Molstead (b) (4)	23 Nov 2020 18:18:35
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:18:35
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Worsening left knee arthritis'	Jennifer Molstead (b) (4)	23 Nov 2020 18:18:35
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '5'	Jennifer Molstead (b) (4)	23 Nov 2020 18:18:35
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:18:35
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:18:35
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'as needed (PRN)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:18:35
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:18:35
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:18:35
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:18:35
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:18:35
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Jennifer Molstead (b) (4)	23 Nov 2020 18:18:35
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:18:35
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:18:35
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:18:35
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:18:35

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:18:35

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:18:35

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE HYDROCHLORIDE, PRODUCTSYNONYM: ATARAX [HYDROXYZINE HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 15:00:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 15:00:12
Data point term sent to Coder	System	24 Nov 2020 14:53:07
User closed query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	System	24 Nov 2020 14:52:18
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'UPDATED' (Site from System).	Traci Hull (b) (4)	24 Nov 2020 14:52:18
User entered 'ATARAX - hydroxyzine hydrochloride' reason for change: Per Query Resolution	Traci Hull (b) (4)	24 Nov 2020 14:52:09
User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4)	24 Nov 2020 13:58:09
Data point term sent to Coder	System	23 Nov 2020 18:20:28
User entered 'atarax'	Jennifer Molstead (b) (4)	23 Nov 2020 18:19:52

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:19:52
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Worsening left knee arthritis'	Jennifer Molstead (b) (4)	23 Nov 2020 18:19:52
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '50'	Jennifer Molstead (b) (4)	23 Nov 2020 18:19:52
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:19:52
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:19:52
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'other (OTHER)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:19:52
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'every three hour as needed'	Jennifer Molstead (b) (4)	23 Nov 2020 18:19:52
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:19:52
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:19:52
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:19:52
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Jennifer Molstead (b) (4)	23 Nov 2020 18:19:52
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:19:52
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:19:52
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:19:52
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:19:52

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:19:52

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:19:52

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 06:38:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 06:38:06
Data point term sent to Coder	System	23 Nov 2020 18:21:31
User entered 'celebrex'	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 18:21:03

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:21:03
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'worsening Left knee arthritis'	Jennifer Molstead (b) (4)	23 Nov 2020 18:21:03
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '200'	Jennifer Molstead (b) (4)	23 Nov 2020 18:21:03
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:21:03
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:21:03
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'twice daily (BID)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:21:03
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:21:03
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:21:03
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:21:03
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:21:03
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Jennifer Molstead (b) (4)	23 Nov 2020 18:21:03
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:21:03
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:21:03
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:21:03
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Nov 2020 18:21:03

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 18:21:03

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Nov 2020 18:21:03

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 11:55:56
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 11:55:56
	(b) (4)	
Data point term sent to Coder	System	23 Nov 2020 18:31:47
User entered 'dulcolax'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:12
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:12
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'worsening left knee arthritis'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:12
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '10'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:12
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:12
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:12
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'as needed (PRN)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:12
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:12
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:12
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:12
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:12
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:12
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:12
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:12
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:12
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:31:12

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:31:12

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:31:12

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ECOTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 07:11:11
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 07:11:11
	(b) (4)	
Data point term sent to Coder	System	23 Nov 2020 18:32:49
User entered 'ecotrin'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'worsening left knee arthritis'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '325'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:31:56
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 18:31:56

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 18:31:56

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Nov 2020 18:31:56

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 06:34:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 06:34:05
Data point term sent to Coder	System	23 Nov 2020 18:33:50
User entered 'famotidine'	Jennifer Molstead (b) (4)	23 Nov 2020 18:32:50

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:32:50
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'worsening left knee arthritis'	Jennifer Molstead (b) (4)	23 Nov 2020 18:32:50
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '20'	Jennifer Molstead (b) (4)	23 Nov 2020 18:32:50
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:32:50
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:32:50
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:32:50
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:32:50
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:32:50
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:32:50
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:32:50
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Jennifer Molstead (b) (4)	23 Nov 2020 18:32:50
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:32:50
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:32:50
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:32:50
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 18:32:50

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 18:32:50

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Nov 2020 18:32:50

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 06:34:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 06:34:05
Data point term sent to Coder	System	23 Nov 2020 18:33:52
User entered 'Famotidine'	Jennifer Molstead (b) (4)	23 Nov 2020 18:33:46

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:33:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'worsening left knee arthritis'	Jennifer Molstead (b) (4)	23 Nov 2020 18:33:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '20/2'	Jennifer Molstead (b) (4)	23 Nov 2020 18:33:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:33:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'mg/ml'	Jennifer Molstead (b) (4)	23 Nov 2020 18:33:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'as needed (PRN)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:33:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:33:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:33:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:33:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:33:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Jennifer Molstead (b) (4)	23 Nov 2020 18:33:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:33:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:33:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:33:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:33:46

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:33:46

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:33:46

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 06:33:47
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 06:33:47
	(b) (4)	
Data point term sent to Coder	System	23 Nov 2020 18:49:19
User entered 'fentanyl'	Jennifer Molstead (b) (4)	23 Nov 2020 18:48:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:48:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'worsening left knee arthritis'	Jennifer Molstead (b) (4)	23 Nov 2020 18:48:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '20'	Jennifer Molstead (b) (4)	23 Nov 2020 18:48:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'ug (ug)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:48:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:48:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'as needed (PRN)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:48:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:48:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:48:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:48:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:48:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Jennifer Molstead (b) (4)	23 Nov 2020 18:48:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:48:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:48:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:48:59
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:48:59

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:48:59

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:48:59

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 07:23:12
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 07:23:12
	(b) (4)	
Data point term sent to Coder	System	23 Nov 2020 18:50:20
User entered 'ferrous sulfate'	Jennifer Molstead (b) (4)	23 Nov 2020 18:49:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:49:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'worsening left knee arthritis'	Jennifer Molstead (b) (4)	23 Nov 2020 18:49:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '325'	Jennifer Molstead (b) (4)	23 Nov 2020 18:49:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:49:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:49:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:49:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:49:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:49:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:49:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:49:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Jennifer Molstead (b) (4)	23 Nov 2020 18:49:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:49:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:49:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:49:46
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 18:49:46

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 18:49:46

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Nov 2020 18:49:46

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: ENEMAS, PRODUCT: SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC, PRODUCTSYNONYM: FLEET ENEMA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 07:25:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 07:25:06
Data point term sent to Coder	System	23 Nov 2020 18:51:21
User entered 'Fleet Enema'	Jennifer Molstead (b) (4)	23 Nov 2020 18:50:45

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:50:45
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'worsening left knee arthritis'	Jennifer Molstead (b) (4)	23 Nov 2020 18:50:45
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '1'	Jennifer Molstead (b) (4)	23 Nov 2020 18:50:45
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:50:45
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'bottle'	Jennifer Molstead (b) (4)	23 Nov 2020 18:50:45
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'as needed (PRN)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:50:45
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:50:45
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Rectal (RECTAL)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:50:45
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:50:45
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:50:45
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Jennifer Molstead (b) (4)	23 Nov 2020 18:50:45
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:50:45
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:50:45
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:50:45
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:50:45

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:50:45

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:50:45

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 06:26:11
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 06:26:11
	(b) (4)	
Data point term sent to Coder	System	23 Nov 2020 18:52:22
User entered 'gabapentin'	Jennifer Molstead (b) (4)	23 Nov 2020 18:51:55
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:51:55
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'worsening left knee arthritis'	Jennifer Molstead (b) (4)	23 Nov 2020 18:51:55
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '400'	Jennifer Molstead (b) (4)	23 Nov 2020 18:51:55
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:51:55
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:51:55
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'twice daily (BID)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:51:55
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:51:55
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:51:55
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:51:55
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:51:55
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Jennifer Molstead (b) (4)	23 Nov 2020 18:51:55
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:51:55
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:51:55
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:51:55
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Nov 2020 18:51:55

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 18:51:55

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Nov 2020 18:51:55

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 19:56:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 19:56:14
Data point term sent to Coder	System	23 Nov 2020 18:53:23
User entered 'Lactated ringers'	Jennifer Molstead (b) (4)	23 Nov 2020 18:53:20

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:53:20
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'worsening left knee arthritis'	Jennifer Molstead (b) (4)	23 Nov 2020 18:53:20
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '1000'	Jennifer Molstead (b) (4)	23 Nov 2020 18:53:20
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'mL (mL)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:53:20
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:53:20
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'other (OTHER)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:53:20
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'continuous'	Jennifer Molstead (b) (4)	23 Nov 2020 18:53:20
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:53:20
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:53:20
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:53:20
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Jennifer Molstead (b) (4)	23 Nov 2020 18:53:20
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:53:20
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:53:20
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:53:20
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:53:20

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:53:20

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:53:20

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LOVENOX [LEVOFLOXACIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 08:19:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	24 Nov 2020 08:19:13
Data point term sent to Coder	System	23 Nov 2020 18:55:28
User entered 'lovenox'	Jennifer Molstead (b) (4)	23 Nov 2020 18:54:32
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:54:32
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'worsening left knee arthritis'	Jennifer Molstead (b) (4)	23 Nov 2020 18:54:32
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '30'	Jennifer Molstead (b) (4)	23 Nov 2020 18:54:32
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:54:32
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:54:32
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:54:32
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:54:32
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:54:32
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:54:32
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:54:32
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Jennifer Molstead (b) (4)	23 Nov 2020 18:54:32
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:54:32
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:54:32
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:54:32
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 18:54:32

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 18:54:32

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Nov 2020 18:54:32

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM HYDROXIDE, PRODUCTSYNONYM: MILK OF MAGNESIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 08:07:10
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 08:07:10
	(b) (4)	
Data point term sent to Coder	System	23 Nov 2020 18:56:29
User entered 'milk of magnesia'	Jennifer Molstead (b) (4)	23 Nov 2020 18:55:39
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:55:39
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'worsening left knee arthritis'	Jennifer Molstead (b) (4)	23 Nov 2020 18:55:39
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '30'	Jennifer Molstead (b) (4)	23 Nov 2020 18:55:39
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'mL (mL)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:55:39
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:55:39
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'as needed (PRN)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:55:39
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:55:39
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:55:39
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:55:39
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:55:39
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Jennifer Molstead (b) (4)	23 Nov 2020 18:55:39
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:55:39
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:55:39
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:55:39
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:55:39

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:55:39

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:55:39

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 07:05:11
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 07:05:11
	(b) (4)	
Data point term sent to Coder	System	23 Nov 2020 18:57:33
User entered 'morphine'	Jennifer Molstead (b) (4)	23 Nov 2020 18:56:58
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:56:58
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'worsening left knee arthritis'	Jennifer Molstead (b) (4)	23 Nov 2020 18:56:58
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '6'	Jennifer Molstead (b) (4)	23 Nov 2020 18:56:58
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:56:58
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:56:58
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'other (OTHER)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:56:58
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'every 3 hours as needed'	Jennifer Molstead (b) (4)	23 Nov 2020 18:56:58
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Intramuscular (INTRAMUSCULAR)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:56:58
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:56:58
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:56:58
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Jennifer Molstead (b) (4)	23 Nov 2020 18:56:58
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:56:58
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:56:58
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:56:58
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:56:58

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:56:58

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:56:58

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 04:28:32
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 04:28:32
	(b) (4)	
Data point term sent to Coder	System	23 Nov 2020 18:58:34
User entered 'oxycodone'	Jennifer Molstead (b) (4)	23 Nov 2020 18:57:54
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:57:54
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'worsening left knee arthritis'	Jennifer Molstead (b) (4)	23 Nov 2020 18:57:54
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '10'	Jennifer Molstead (b) (4)	23 Nov 2020 18:57:54
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:57:54
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:57:54
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'as needed (PRN)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:57:54
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:57:54
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:57:54
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:57:54
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:57:54
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '0'	Jennifer Molstead (b) (4)	23 Nov 2020 18:57:54
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:57:54
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:57:54
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:57:54
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:57:54

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:57:54

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:57:54

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:00:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:00:10
Data point term sent to Coder	System	23 Nov 2020 19:59:32
User entered 'HYDROCODONE/ACETAMINOPHEN' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 19:58:52
Data point term sent to Coder	System	23 Nov 2020 19:57:30
User entered 'HYDROCODONE'	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 19:57:23
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 19:54:26
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 18:58:31

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:09
User entered 'No (N)'	Tammy Kohn (b) (4)	23 Nov 2020 19:57:23
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:54:26
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	23 Nov 2020 18:58:31
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:08
User entered 'LEFT KNEE REPLACEMENT (ARTHROPLASTY)'	Tammy Kohn (b) (4)	23 Nov 2020 19:57:23
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:54:26
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	23 Nov 2020 18:58:31
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:06
User entered '5/325' reason for change: Data Entry Error	Tammy Kohn (b) (4)	23 Nov 2020 19:58:52
User entered '5'	(b) (4)	
	Tammy Kohn (b) (4)	23 Nov 2020 19:57:23
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:54:26
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	23 Nov 2020 18:58:31
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:05
User entered 'mg (mg)'	Tammy Kohn (b) (4)	23 Nov 2020 19:57:23
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:54:26
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	23 Nov 2020 18:58:31
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:03
User entered empty.	Tammy Kohn (b) (4)	23 Nov 2020 19:57:23
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:54:26
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	23 Nov 2020 18:58:31
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:02
User entered 'as needed (PRN)'	Tammy Kohn (b) (4)	23 Nov 2020 19:57:23
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:54:26
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	23 Nov 2020 18:58:31
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:01
User entered empty.	Tammy Kohn (b) (4)	23 Nov 2020 19:57:23
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:54:26
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	23 Nov 2020 18:58:31
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:09:59
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4)	23 Nov 2020 19:57:23
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:54:26
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	23 Nov 2020 18:58:31
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:09:58
User entered empty.	Tammy Kohn (b) (4)	23 Nov 2020 19:57:23
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:54:26
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	23 Nov 2020 18:58:31
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:09:55
User entered '12 Oct 2020'	Tammy Kohn (b) (4)	23 Nov 2020 19:57:23
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:54:26
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	23 Nov 2020 18:58:31
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:09:56
User entered '0'	Tammy Kohn (b) (4)	23 Nov 2020 19:57:23
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:54:26
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	23 Nov 2020 18:58:31
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered 'No (N)'	Tammy Kohn (b) (4)	23 Nov 2020 19:57:23
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:54:26
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	23 Nov 2020 18:58:31
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:11:05
User entered '22 Oct 2020'	Tammy Kohn (b) (4)	23 Nov 2020 19:57:23
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:54:26
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	23 Nov 2020 18:58:31
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:09:52
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	23 Nov 2020 19:57:23
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:54:26
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	23 Nov 2020 18:58:31
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:57:23
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 19:54:26
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 18:58:31

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:57:23
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 19:54:26
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 18:58:31

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:57:23
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 19:54:26
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 18:58:31

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:24
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM, PRODUCTSYNONYM: AMOXICILLIN/CLAVULANIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 20:03:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 20:03:04
Data point term sent to Coder	System	23 Nov 2020 20:01:34
User entered 'AMOXICILLIN/CLAVULANIC ACID'	Tammy Kohn (b) (4)	23 Nov 2020 20:00:55
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:59:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Nov 2020 19:58:34

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:25
User entered 'No (N)'	Tammy Kohn (b) (4)	23 Nov 2020 20:00:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:59:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Nov 2020 19:58:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:26
User entered 'LEFT KNEE REPLACEMENT (ARTHOPLASTY)'	Tammy Kohn (b) (4)	23 Nov 2020 20:00:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:59:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Nov 2020 19:58:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:27
User entered '125/875'	Tammy Kohn (b) (4)	23 Nov 2020 20:00:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:59:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Nov 2020 19:58:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:28
User entered 'mg (mg)'	Tammy Kohn (b) (4)	23 Nov 2020 20:00:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:59:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Nov 2020 19:58:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:30
User entered empty.	Tammy Kohn (b) (4)	23 Nov 2020 20:00:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:59:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Nov 2020 19:58:34
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:31
User entered 'once daily (QD)'	Tammy Kohn (b) (4)	23 Nov 2020 20:00:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:59:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Nov 2020 19:58:34
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:33
User entered empty.	Tammy Kohn (b) (4)	23 Nov 2020 20:00:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:59:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Nov 2020 19:58:34
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:35
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4)	23 Nov 2020 20:00:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:59:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Nov 2020 19:58:34
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:36
User entered empty.	Tammy Kohn (b) (4)	23 Nov 2020 20:00:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:59:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Nov 2020 19:58:34
	(b) (4)	

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:37
User entered '12 Oct 2020'	Tammy Kohn (b) (4)	23 Nov 2020 20:00:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:59:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Nov 2020 19:58:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:39
User entered '0'	Tammy Kohn (b) (4)	23 Nov 2020 20:00:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:59:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Nov 2020 19:58:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:40
User entered 'No (N)'	Tammy Kohn (b) (4)	23 Nov 2020 20:00:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:59:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Nov 2020 19:58:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:41
User entered '22 Oct 2020'	Tammy Kohn (b) (4)	23 Nov 2020 20:00:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:59:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Nov 2020 19:58:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:10:42
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	23 Nov 2020 20:00:55
	(b) (4)	
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Nov 2020 19:59:32
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Nov 2020 19:58:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 20:00:55
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 19:59:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 19:58:34

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 20:00:55
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 19:59:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 19:58:34

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:23:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Nov 2020 20:00:55
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 19:59:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 19:58:34

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:23:58

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User closed query 'Per source - subject had left knee replacement - for left knee arthritis on 12 Oct 2020. Please ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4) (b) (4), (b) (6)	24 Nov 2020 20:55:24 24 Nov 2020 20:55:23
Query 'Per source - subject had left knee replacement - for left knee arthritis on 12 Oct 2020. Please ' answered with 'data updated' (Site from CRA). DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4) Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 16:00:26 23 Nov 2020 15:58:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	23 Nov 2020 15:58:53
User opened query 'Per source - subject had left knee replacement - for left knee arthritis on 12 Oct 2020. Please ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	20 Nov 2020 19:57:50 20 Nov 2020 19:54:58
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Sep 2020 19:42:42

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:23:58

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:21:15
User entered '12 Oct 2020'	Tammy Kohn (b) (4)	23 Nov 2020 16:00:11
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:23:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:21:15
User entered 'left knee replacement'	Tammy Kohn (b) (4)	23 Nov 2020 16:00:11
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:21:15
User entered 'Other (OTHER)'	Tammy Kohn (b) (4)	23 Nov 2020 16:00:11
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:23:58

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:21:15
User entered 'left knee replacement due to left knee arthritis'	Tammy Kohn (b) (4)	23 Nov 2020 16:00:11
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:23:58

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:21:15
User entered '13 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:08:02
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:23:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:21:15
User entered 'complete Blood Count'	Jennifer Molstead (b) (4)	23 Nov 2020 18:08:02
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:21:15
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4)	23 Nov 2020 18:08:02
	(b) (4)	

US3402139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:23:58

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:21:15
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:08:02
	(b) (4)	

US3402139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:23:58

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:21:15
User entered '14 Oct 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 18:08:23
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:23:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:21:15
User entered 'Complete Blood Count'	Jennifer Molstead (b) (4)	23 Nov 2020 18:08:23
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:23:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:21:15
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 18:08:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 18:08:28
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	23 Nov 2020 18:08:28
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 18:08:23
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:08:23
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:23:58

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:21:15
User entered empty.	Jennifer Molstead (b) (4)	23 Nov 2020 18:08:23
	(b) (4)	

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Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'USA-US059-2020-MRNA-1273-P301000014'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Yes (Y)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Yes (Y)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Frank'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Eder'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered '1290 Upper Front Street'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Binghamton'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'NY'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered '13901'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:45:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
User entered 'US'	System	27 Oct 2020 14:25:57

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 13:43:10
User entered '3'	System	18 Nov 2020 14:45:11
User entered '2'	System	09 Nov 2020 19:27:50
User entered '1'	System	27 Oct 2020 14:25:57

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'USA-US059-2020-MRNA-1273-P301000014'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Yes (Y)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Yes (Y)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Frank'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Eder'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered '1290 Upper Front Street'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Binghamton'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'NY'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered '13901'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:45:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
User entered 'US'	System	27 Oct 2020 14:25:57

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 13:43:10
User entered '3'	System	18 Nov 2020 14:45:11
User entered '2'	System	09 Nov 2020 19:27:50
User entered '1'	System	27 Oct 2020 14:25:57

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:23:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
User entered '27/Oct/2020 10:25'	System	27 Oct 2020 14:25:57

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:23:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:45:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
User entered '1'	(b) (4), (b) (6)	27 Oct 2020 14:25:57

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'USA-US059-2020-MRNA-1273-P301000014'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Yes (Y)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Yes (Y)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Frank'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Eder'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered '1290 Upper Front Street'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Binghamton'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'NY'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered '13901'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:45:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
User entered 'US'	System	27 Oct 2020 14:25:57

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 13:43:10
User entered '3'	System	18 Nov 2020 14:45:11
User entered '2'	System	09 Nov 2020 19:27:50
User entered '1'	System	27 Oct 2020 14:25:57

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:23:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '09/Nov/2020 14:27'	System	09 Nov 2020 19:27:50

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:23:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:45:02
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 19:27:50

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'USA-US059-2020-MRNA-1273-P301000014'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Yes (Y)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Yes (Y)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Frank'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Eder'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered '1290 Upper Front Street'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Binghamton'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'NY'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered '13901'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:45:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
User entered 'US'	System	27 Oct 2020 14:25:57

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 13:43:10
User entered '3'	System	18 Nov 2020 14:45:11
User entered '2'	System	09 Nov 2020 19:27:50
User entered '1'	System	27 Oct 2020 14:25:57

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:23:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:20:37
User entered '18/Nov/2020 09:45'	System	18 Nov 2020 14:45:11

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:23:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:40:01
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:20:42
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 14:45:11

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'USA-US059-2020-MRNA-1273-P301000014'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

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Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Yes (Y)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Yes (Y)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'No (N)'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Frank'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Eder'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered '1290 Upper Front Street'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'Binghamton'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered 'NY'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
Reviewed for Safety.	(b) (4), (b) (6)	27 Oct 2020 14:25:50
User entered '13901'	System	27 Oct 2020 14:19:05

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:45:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:02:06
User entered 'US'	System	27 Oct 2020 14:25:57

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 13:43:10
User entered '3'	System	18 Nov 2020 14:45:11
User entered '2'	System	09 Nov 2020 19:27:50
User entered '1'	System	27 Oct 2020 14:25:57

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:23:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 08:43'	System	24 Nov 2020 13:43:10

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:23:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 13:43:10