

US3402284 (Prod: Meridian Clinical Research, LLC)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:25:59

All time stamps listed in this document are displayed in GMT

US3402284

Form: Participant Creation

Generated On: 26 Nov 2020 09:25:59

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:59

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	08 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 09:25:59

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	58
Age Units	YEARS
Age (Derived)	59
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 09:25:59

Date of Informed Consent (<i>dd MMM yyyy</i>)	08 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 09:25:59

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:25:59

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:59

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:59

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

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:59

Condition	OSTEOARTHRITIS LEFT HIP
Start date (dd MMM yyyy)	UN UNK 1982
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 1982
Start Year (derived)	1982
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:59

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:59

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:59

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

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:59

Condition	GOUT (RIGHT FOOT)
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:59

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

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:59

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

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:59

Condition	GALLSTONES
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	08 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	07:58 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 07:58
Height (<i>xxx.x</i>)	187.2 cm
Weight (<i>xxx.x</i>)	139.8 kg
BMI (<i>xxx.x</i>)	39.89289 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	81 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

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

CUSTODIAN (b) (6)

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

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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)	True
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 09:25:59

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	08 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 09:25:59

What was the date of randomization? (dd MMM yyyy) 08 AUG 2020

What was the participant's randomization number? 143108

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:59

Height	187.2 cm
Weight	139.8 kg

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

Height	187.2 cm
Weight	139.8 kg
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	08 AUG 2020
Time of assessment (00:00-23:59)	07:58 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 07:58
Temperature (xxx.x)	36.6 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 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 09:25:59

Height	187.2 cm
Weight	139.8 kg
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	08 AUG 2020
Time of assessment (00:00-23:59)	09:25 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 09:25
Temperature (xxx.x)	36.6 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 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 09:25:59

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) 08 AUG 2020

What was the treatment time? (00:00-23:59) 08:53 (24 HR)

Treatment Date and Time (derived) 08 AUG 2020 08:53

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 09:25:59

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	08 AUG 2020
Collection time (<i>00:00-23:59</i>)	08:21 (24 HR)
Collection date and time (derived)	08 AUG 2020 08:21

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:25:59

Collection date (dd MMM yyyy)			08 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:10	08 AUG 2020 08:10
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

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 09:25:59

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

08 AUG 2020 09:18

PC Open Date & Time

08 AUG 2020 09:13

PC Close Date & Time

08 AUG 2020 11:43

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

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

97.4 °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	08 AUG 2020 17:10
PC Open Date & Time	08 AUG 2020 12:38
PC Close Date & Time	09 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 19:10

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:59

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

97.7 °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

10 AUG 2020 18:58

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 17:12

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:59

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

96.7 °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

12 AUG 2020 18:40

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 19:48

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:59

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

97.7 °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

14 AUG 2020 20:29

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

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

08 AUG 2020 09:17

PC Open Date & Time

08 AUG 2020 09:13

PC Close Date & Time

08 AUG 2020 11:43

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

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

08 AUG 2020 17:11

PC Open Date & Time

08 AUG 2020 12:38

PC Close Date & Time

09 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:59

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

09 AUG 2020 19:10

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:59

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

10 AUG 2020 18:59

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:59

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

11 AUG 2020 17:13

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:59

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

12 AUG 2020 18:41

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:59

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

13 AUG 2020 19:49

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:59

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

14 AUG 2020 20:30

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 09:16
PC Open Date & Time	08 AUG 2020 09:13
PC Close Date & Time	08 AUG 2020 11:43

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 17:12
PC Open Date & Time	08 AUG 2020 12:38
PC Close Date & Time	09 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

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 ☒

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

Yes ☐	
PC Time stamp	09 AUG 2020 19:11
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

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 ☒

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

Yes ☐	
PC Time stamp	10 AUG 2020 18:59
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

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 ☒

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

Yes ☐	
PC Time stamp	11 AUG 2020 17:13
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

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 ☒

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

Yes ☐	
PC Time stamp	12 AUG 2020 18:41
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

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 ☒

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

Yes ☐	
PC Time stamp	13 AUG 2020 19:50
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

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 ☒

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

Yes ☐	
PC Time stamp	14 AUG 2020 20:31
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 15 AUG 2020 22:49

PC Open Date & Time 15 AUG 2020 12:00

PC Close Date & Time 16 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 16 AUG 2020 19:17

PC Open Date & Time 16 AUG 2020 12:00

PC Close Date & Time 17 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

17 AUG 2020 17:47

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

18 AUG 2020 21:09

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 19 AUG 2020 18:52

PC Open Date & Time 19 AUG 2020 12:00

PC Close Date & Time 20 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 20 AUG 2020 18:42

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

21 AUG 2020 19:59

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

22 AUG 2020 17:10

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 8

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 15 AUG 2020 22:49

PC Open Date & Time 15 AUG 2020 12:00

PC Close Date & Time 16 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 9

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 16 AUG 2020 19:17

PC Open Date & Time 16 AUG 2020 12:00

PC Close Date & Time 17 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 10

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 17 AUG 2020 17:48

PC Open Date & Time 17 AUG 2020 12:00

PC Close Date & Time 18 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 11

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 18 AUG 2020 21:09

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 12

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 19 AUG 2020 18:52

PC Open Date & Time 19 AUG 2020 12:00

PC Close Date & Time 20 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 13

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 20 AUG 2020 18:42

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 14

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 21 AUG 2020 20:00

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 15

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

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 22 AUG 2020 17:11

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	15 AUG 2020 22:50

PC Open Date & Time	15 AUG 2020 12:00

PC Close Date & Time	16 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 16 AUG 2020 19:17

PC Open Date & Time 16 AUG 2020 12:00

PC Close Date & Time 17 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 17 AUG 2020 17:48

PC Open Date & Time 17 AUG 2020 12:00

PC Close Date & Time 18 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 18 AUG 2020 21:09

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 19 AUG 2020 18:53

PC Open Date & Time 19 AUG 2020 12:00

PC Close Date & Time 20 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 20 AUG 2020 18:42

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	15 AUG 2020 22:50
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	16 AUG 2020 19:18
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	17 AUG 2020 17:48
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	18 AUG 2020 21:09
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	19 AUG 2020 18:53
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	20 AUG 2020 18:43
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	21 AUG 2020 20:00
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	22 AUG 2020 17:11
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3402284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

Was Contact Attempted?

Yes ☒

No ☐

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

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402284

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:59

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	15:36 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 15:36
Temperature (xxx.x)	36.5 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	16:50 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 16:50
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)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3402284

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

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)	10 SEP 2020
What was the treatment time? (00:00-23:59)	16:17 (24 HR)
Treatment Date and Time (derived)	10 SEP 2020 16:17
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

US3402284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:59

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	10 SEP 2020
Collection time (<i>00:00-23:59</i>)	15:52 (24 HR)
Collection date and time (derived)	10 SEP 2020 15:52

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:25:59

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:55	10 SEP 2020 15:55
Nasopharyngeal Swab 2	No		

US3402284

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

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 10 SEP 2020 16:52

PC Open Date & Time 10 SEP 2020 16:37

PC Close Date & Time 10 SEP 2020 19:07

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

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 98.2 °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	10 SEP 2020 21:29
PC Open Date & Time	10 SEP 2020 20:02
PC Close Date & Time	11 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

11 SEP 2020 19:53

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:59

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

12 SEP 2020 19:07

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:59

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 20:32

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:59

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	98.4 °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):

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

PC Time Stamp	14 SEP 2020 19:53
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:59

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	97.6 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

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

PC Time Stamp	15 SEP 2020 19:33
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 20:04

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

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

10 SEP 2020 16:53

PC Open Date & Time

10 SEP 2020 16:37

PC Close Date & Time

10 SEP 2020 19:07

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

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

10 SEP 2020 21:30

PC Open Date & Time

10 SEP 2020 20:02

PC Close Date & Time

11 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:59

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

11 SEP 2020 19:54

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:59

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

12 SEP 2020 19:08

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:59

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

13 SEP 2020 20:33

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:59

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

14 SEP 2020 19:53

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:59

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

15 SEP 2020 19:33

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:59

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

16 SEP 2020 20:04

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 16:54
PC Open Date & Time	10 SEP 2020 16:37
PC Close Date & Time	10 SEP 2020 19:07

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 21:31
PC Open Date & Time	10 SEP 2020 20:02
PC Close Date & Time	11 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

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 ☒

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

Yes ☐	
PC Time stamp	11 SEP 2020 19:55
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

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 ☒

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

Yes ☐	
PC Time stamp	12 SEP 2020 19:08
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

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 ☒

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

Yes ☐	
PC Time stamp	13 SEP 2020 20:34
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

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 ☒

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

Yes ☐	
PC Time stamp	14 SEP 2020 19:54
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

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 ☒

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

Yes ☐	
PC Time stamp	15 SEP 2020 19:35
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

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 ☒

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

Yes ☐	
PC Time stamp	16 SEP 2020 20:05
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 8

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 17 SEP 2020 19:44

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 9

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 18 SEP 2020 20:53

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 10

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 19 SEP 2020 19:25

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 11

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 21 SEP 2020 05:08

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 12

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 21 SEP 2020 15:29

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 13

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 14

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 24 SEP 2020 08:18

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 15

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 25 SEP 2020 11:40

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 16

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 26 SEP 2020 00:00

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 17

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 26 SEP 2020 17:12

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 18

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 27 SEP 2020 19:12

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 19

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 20

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 29 SEP 2020 15:32

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 21

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

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 22

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 01 OCT 2020 20:31

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 23

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 02 OCT 2020 20:26

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 24

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

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 03 OCT 2020 20:47

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 17 SEP 2020 19:44

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 18 SEP 2020 20:53

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 19 SEP 2020 19:25

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 21 SEP 2020 05:08

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 21 SEP 2020 15:28

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 24 SEP 2020 08:19

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 25 SEP 2020 11:40

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 26 SEP 2020 00:00

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 26 SEP 2020 17:11

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 27 SEP 2020 19:12

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 29 SEP 2020 15:32

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	17 SEP 2020 19:45
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	18 SEP 2020 20:53
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	19 SEP 2020 19:25
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	21 SEP 2020 05:07
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	21 SEP 2020 15:28
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 13

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐ Yes ☒
PC Time stamp	24 SEP 2020 08:19
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	25 SEP 2020 11:39
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	26 SEP 2020 00:00
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	26 SEP 2020 17:11
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	27 SEP 2020 19:12
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	29 SEP 2020 15:31
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 21

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 22
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	01 OCT 2020 20:31
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 23
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	02 OCT 2020 20:26
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT	DAY 24
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	03 OCT 2020 20:47
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3402284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

Was Contact Attempted?

Yes ☒

No ☐

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

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402284

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

Was Contact Attempted?

Yes ☒

No ☐

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

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402284

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

Was Contact Attempted?

Yes ☒

No ☐

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

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402284

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:59

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	08 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	08 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	15:04 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 15:04
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	88 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402284

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:59

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.

US3402284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:59

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	08 OCT 2020
Collection time (<i>00:00-23:59</i>)	15:17 (24 HR)
Collection date and time (derived)	08 OCT 2020 15:17

US3402284

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	08 OCT 2020 14:28:34
Patient Cloud Open Date & Time	08 OCT 2020 00:01
Patient Cloud Close Date & Time	12 OCT 2020 23:59

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 OCT 2020 10:29:38
Patient Cloud Open Date & Time	15 OCT 2020 00:01
Patient Cloud Close Date & Time	19 OCT 2020 23:59

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

22 OCT 2020 20:21:55

Patient Cloud Open Date & Time

22 OCT 2020 00:01

Patient Cloud Close Date & Time

26 OCT 2020 23:59

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

05 NOV 2020 15:45:33

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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	12 NOV 2020 10:33:30
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 NOV 2020 16:48:31

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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°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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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°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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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°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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

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27 MAY 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

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17 JUN 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

Date and time of submission

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27 JUN 2022 00:01

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01 JUL 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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°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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

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08 JUL 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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25 JUL 2022 00:01

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29 JUL 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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05 AUG 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

Date and time of submission

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08 AUG 2022 00:01

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12 AUG 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

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19 AUG 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

Date and time of submission

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22 AUG 2022 00:01

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26 AUG 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

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02 SEP 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

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16 SEP 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2022 23:59

US3402284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

Was Contact Attempted?

Yes ☒

No ☐

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

03 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402284

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402284

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:25:59

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3402284

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:25:59

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

AEID	USA-US059-2020-MRNA-1273-P30 1000004
Adverse event	KIDNEY STONE
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)	22 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	23 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	23 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	420 of 2426

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

SUBJECT HAD SEVERE PAIN
THE MORNING OF 22SEP2020.
HE WENT TO THE ER AND WAS
ADMITTED FOR EMERGENCY
LITHOTRIPSY. PROCEDURE
WITH STENT PLACEMENT WAS
PERFORMED. SUBJECT WAS
KEPT OVER NIGHT AND
DISCHARGED 23SEP2020 AT
11:30. SUBJECT HAD A WHITE
BLOOD COUNT OF 15.1UL,
NORMAL IS 10.3 UL, CT
ABDOMEN AND PELVIS: LEFT
OBSTRUCTIVE UROPATHY DUE
TO 4.5MM DISTAL URETERAL
STONE. SUBJECT WAS GIVEN
CEFTRIAZONE 1G IV DAILY,
HEPARIN 5,000 UNITS Q12H,
KETOROLAC 30MG IV Q6H,
TAMSULOSIN 0.4 MG PO DAILY.
SUBJECT WAS ALSO GIVEN
SODIUM CHLORIDE 0.9%
100ML/HR. COVID-19 TESTING
WAS PERFORMED 22SEP2020
RESULT WAS NEGATIVE.

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:25:59

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

Yes ☒

No ☐

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

Name of Medication	NAPROXEN
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOARTHRITIS LEFT HIP
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 ☐

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

	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 1982
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	☒

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

Name of Medication	CYCLOBENZAPRINE
Prophylaxis	Yes ☐ No ☒
Indication	PINCHED NERVE LEFT SHOULDER
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 ☐

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

Name of Medication	ATORVASTATIN CALCIUM
Prophylaxis	Yes ☐ No ☒
Indication	HYPERCHOLESTEROLEMIA
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 ☐

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

Name of Medication	ALLOPURINOL
Prophylaxis	Yes ☐ No ☒
Indication	GOUT
Dose per administration	300
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

	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 2005	
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 ☒	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☒
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	MILD MUSCLE AND JOINT ACHES
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 ☐

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

	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)		13 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 14 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	☐

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

Name of Medication	HYDROCHLOROTHIAZIDE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	12.5
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 ☐

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☒
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	23 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

Name of Medication	HEPARIN
Prophylaxis	Yes ☐ No ☒
Indication	KIDNEY STONE
Dose per administration	5000
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 ☐

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

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)	22 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒
If not Ongoing, End date (dd MMM yyyy)	23 SEP 2020
Was this medication taken for solicited event?	Yes ☐ No ☒
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☒

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		23 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:25:59

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:25:59

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
22 SEP 2020	LITHOTRIPSY	Adverse Event	
22 SEP 2020	CT OF ABDOMEN AND PELVIS	Adverse Event	
22 SEP 2020	COMPLETE BLOOD COUNT	Adverse Event	

US3402284

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:25:59

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

US3402284

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:25:59

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 ☐

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

SAEID	USA-US059-2020-MRNA-1273-P301000004
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

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:25:59

SAEID	USA-US059-2020-MRNA-1273-P301000004
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)	25/SEP/2020 15:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:25:59

SAEID	USA-US059-2020-MRNA-1273-P301000004
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)	13/OCT/2020 13:01
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

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:25:59

SAEID	USA-US059-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	14/OCT/2020 10:03
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

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:25:59

SAEID	USA-US059-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	30/OCT/2020 10:36
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

US3402284 (Prod: Meridian Clinical Research, LLC)

US3402284

Form: Participant Creation

Generated On: 26 Nov 2020 09:25:59

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3402284'	RWS_ENDPOINT ENDPOINT (b) (4) 	08 Aug 2020 12:10:27

US3402284

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 12:59:56

US3402284

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '08 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	08 Aug 2020 12:10:28

US3402284

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 12:59:56

US3402284

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:59

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	08 Aug 2020 12:59:56

US3402284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered (b) (6) 1961'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	08 Aug 2020 12:10:29

US3402284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:59

[Age](#)

Audit	User	Time (GMT)
User entered '58'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:00:07

US3402284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:59

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	08 Aug 2020 13:00:07

US3402284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:59

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '59'	System	08 Aug 2020 13:00:42

US3402284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:59

Sex

Audit	User	Time (GMT)
User entered 'Male (M)'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:00:07

US3402284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:59

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:00:07

US3402284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:59

[White](#)

Audit	User	Time (GMT)
User entered '1'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:00:07

US3402284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:59

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:00:07

US3402284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:59

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:00:07

US3402284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:59

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:00:07

US3402284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:59

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:00:07

US3402284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:59

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:00:07

US3402284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:59

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:00:07

US3402284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:59

Unknown

Audit	User	Time (GMT)
User entered '0'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:00:07

US3402284

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:59

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:00:07

US3402284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 12:40:47
User entered '8 Aug 2020'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:00:42

US3402284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	08 Aug 2020 13:00:42

US3402284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '2020'	System	08 Aug 2020 13:00:42

US3402284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:59

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:00:42

US3402284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:00:42

US3402284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:00:42

US3402284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:59

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:00:42

US3402284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:59

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:00:42

US3402284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:59

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	08 Aug 2020 12:10:28

US3402284

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:59

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 13:00:47

US3402284

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:00:47

US3402284

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:25:59

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User closed query 'Per source - please verify and add to medical history - L Hip Replacement - Perthes Disease - UNK/2016.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:11:07
	(b) (4), (b) (6)	24 Nov 2020 21:11:00
Query 'Per source - please verify and add to medical history - L Hip Replacement - Perthes Disease - UNK/2016.' answered with 'This is in direct correlation to the Left hip osteoarthritis' (Site from CRA).	Jennifer Molstead (b) (4)	23 Nov 2020 20:57:15
User opened query 'Per source - please verify and add to medical history - L Hip Replacement - Perthes Disease - UNK/2016.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 20:43:32
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 20:31:16

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:59

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:38:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:38:49
Data point term sent to Coder	System	08 Aug 2020 20:38:08
Coding entries removed.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:37:52
User entered 'DIABETES TYPE 2' reason for change: Data Entry Error	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:37:52
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:32:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:32:48
Data point term sent to Coder	System	08 Aug 2020 20:32:06
User entered 'DIABETES'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:31:40

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:31:40

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:31:40

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:31:40

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:31:40

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:31:40

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	08 Aug 2020 20:31:40

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '2019'	System	08 Aug 2020 20:31:40

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 20:31:40

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 20:31:40

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:59

[Condition](#)

Audit	User	Time (GMT)
User closed query 'CDM RQ: Previous response states 'CHOLECYSTECTOMY due to gallstones', however there is no record of Gallstones in the patients Medical History. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 14:46:49
Query 'CDM RQ: Previous response states 'CHOLECYSTECTOMY due to gallstones', however there is no record of Gallstones in the patients Medical History. Please verify and update as appropriate.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	08 Oct 2020 17:50:20
User opened query 'CDM RQ: Previous response states 'CHOLECYSTECTOMY due to gallstones', however there is no record of Gallstones in the patients Medical History. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 13:24:50
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 13:24:50
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'CHOLECYSTECTOMY due to gallstones' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	30 Sep 2020 12:43:09
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 17:31:21
User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:32:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:32:48
Data point term sent to Coder	System	08 Aug 2020 20:32:06
User entered 'CHOLECYSTECTOMY'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:32:02

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'UN Mar 2019'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:32:02

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:32:02

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 20:33:17
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 20:32:02

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'UN Mar 2019' reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 20:33:17
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:32:02

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:32:02

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Mar 2019'	System	08 Aug 2020 20:32:02

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '2019'	System	08 Aug 2020 20:32:02

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Mar 2019'	System	08 Aug 2020 20:33:17
User entered empty.	System	08 Aug 2020 20:32:02

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '2019'	System	08 Aug 2020 20:33:17
User entered empty.	System	08 Aug 2020 20:32:02

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:59

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:34:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:34:48
Data point term sent to Coder	System	08 Aug 2020 20:33:06
User entered 'OSTEOARTHRITIS LEFT HIP'	Traci Hull (b) (4)	08 Aug 2020 20:32:22
	(b) (4)	

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'UN UNK 1982'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:32:22

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:32:22

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:32:22

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:32:22

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:32:22

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Jan 1982'	System	08 Aug 2020 20:32:22

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '1982'	System	08 Aug 2020 20:32:22

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 20:32:22

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 20:32:22

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:59

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:34:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:34:48
Data point term sent to Coder	System	08 Aug 2020 20:33:06
User entered 'HYPERTENSION'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:32:32

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'UN UNK 2000' reason for change:	Tammy Kohn (b) (4)	26 Sep 2020 15:06:47
Data Entry Error	(b) (4)	
User entered 'UN UNK 2017'	Traci Hull (b) (4)	08 Aug 2020 20:32:32
	(b) (4)	

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:32:32

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:32:32

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:32:32

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:32:32

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	26 Sep 2020 15:06:47
User entered 'Jan 2017'	System	08 Aug 2020 20:32:32

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '2000'	System	26 Sep 2020 15:06:47
User entered '2017'	System	08 Aug 2020 20:32:32

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 20:32:32

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 20:32:32

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:59

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Nerve compression, LLT: Pinched nerve - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 16:52:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 16:52:42
Data point term sent to Coder	System	08 Aug 2020 20:33:06
User entered 'PINCHED NERVE LEFT SHOULDER'	Traci Hull (b) (4)	08 Aug 2020 20:32:52

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'UN Feb 2020'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:32:52

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:32:52

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:32:52

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:32:52

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:32:52

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Feb 2020'	System	08 Aug 2020 20:32:52

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '2020'	System	08 Aug 2020 20:32:52

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 20:32:52

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 20:32:52

US3402284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:59

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:34:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:34:48
Data point term sent to Coder	System	08 Aug 2020 20:34:07
User entered 'HYPERCHOLESTEROLEMIA'	Traci Hull (b) (4)	08 Aug 2020 20:33:45

US3402284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'UN May 2020'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:33:45

US3402284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:33:45

US3402284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:33:45

US3402284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:33:45

US3402284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:33:45

US3402284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'May 2020'	System	08 Aug 2020 20:33:45

US3402284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '2020'	System	08 Aug 2020 20:33:45

US3402284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 20:33:45

US3402284

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 20:33:45

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:59

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location of gout. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 13:25:14
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 12:41:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	30 Sep 2020 12:41:47
Data point term sent to Coder	System	30 Sep 2020 12:41:20
Query 'Per DM CLR: Please specify the location of gout. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'GOUT (right foot)' (Site from DM).	Tammy Kohn (b) (4)	30 Sep 2020 12:41:12
Coding entries removed.	(b) (4)	
User entered 'GOUT (right foot)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	30 Sep 2020 12:41:06
User opened query 'Per DM CLR: Please specify the location of gout. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 17:31:44
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\23.0.	Coder Import (b) (4)	08 Aug 2020 20:34:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	08 Aug 2020 20:34:48
Data point term sent to Coder	System	08 Aug 2020 20:34:07
User entered 'GOUT'	Traci Hull (b) (4)	08 Aug 2020 20:33:58

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'UN UNK 2005'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:33:58

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:33:58

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:33:58

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:33:58

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:33:58

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	08 Aug 2020 20:33:58

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '2005'	System	08 Aug 2020 20:33:58

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 20:33:58

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 20:33:58

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:59

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:35:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:35:49
Data point term sent to Coder	System	08 Aug 2020 20:35:07
User entered 'SLEEP APNEA'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:34:14

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:34:14

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:34:14

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:34:14

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:34:14

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:34:14

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	08 Aug 2020 20:34:14

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '2016'	System	08 Aug 2020 20:34:14

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 20:34:14

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 20:34:14

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:59

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:11:28
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Epiphyseal disorders, PT: Perthes disease, LLT: Perthes disease - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:35:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Aug 2020 20:35:49
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 20:35:07
User entered 'PERTHES DISEASE'	Traci Hull (b) (4)	08 Aug 2020 20:34:32
	(b) (4)	

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per source start date was UNK 2016 - please verify and update accordingly. ' answered with 'DATA UPDATED' (Site from CRA).	Tammy Kohn (b) (4)	24 Nov 2020 22:21:46
DataPoint Un-verified.	(b) (4)	
	Tammy Kohn (b) (4)	24 Nov 2020 22:21:39
	(b) (4)	
User entered 'UN UNK 2016' reason for change:	Tammy Kohn (b) (4)	24 Nov 2020 22:21:39
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:11:29
	(b) (4), (b) (6)	24 Nov 2020 21:11:25
User opened query 'Per source start date was UNK 2016 - please verify and update accordingly. ' (Site from CRA).		
User entered 'UN UNK 2017'	Traci Hull (b) (4)	08 Aug 2020 20:34:32
	(b) (4)	

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:11:30
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 20:34:32
	(b) (4)	

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:11:31
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 20:34:32
	(b) (4)	

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:11:32
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:34:32
	(b) (4)	

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:11:34
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 20:34:32
	(b) (4)	

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	24 Nov 2020 22:21:39
User entered 'Jan 2017'	System	08 Aug 2020 20:34:32

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '2016'	System	24 Nov 2020 22:21:39
User entered '2017'	System	08 Aug 2020 20:34:32

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 20:34:32

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 20:34:32

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:59

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallstones - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:45:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:45:24
Data point term sent to Coder	System	08 Oct 2020 17:50:40
User entered 'Gallstones'	Tammy Kohn (b) (4)	08 Oct 2020 17:49:53
	(b) (4)	

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Tammy Kohn (b) (4) (b) (4)	08 Oct 2020 17:49:53

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	08 Oct 2020 17:49:53

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	08 Oct 2020 17:49:53

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	08 Oct 2020 17:50:09
User entered 'UN UNK 2019' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	08 Oct 2020 17:50:09
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	08 Oct 2020 17:49:53
User entered 'UN UNK 2011'	Tammy Kohn (b) (4) (b) (4)	08 Oct 2020 17:49:53

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tammy Kohn (b) (4) (b) (4)	08 Oct 2020 17:49:53

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	08 Oct 2020 17:49:53

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '2018'	System	08 Oct 2020 17:49:53

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	08 Oct 2020 17:50:09
User entered 'Jan 2011'	System	08 Oct 2020 17:49:53

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '2019'	System	08 Oct 2020 17:50:09
User entered '2011'	System	08 Oct 2020 17:49:53

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:35:25

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:43:29
User entered '8 Aug 2020'	Traci Hull (b) (4)	08 Aug 2020 20:35:25

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '07:58'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:35:25

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '08 Aug 2020 07:58'	System	11 Nov 2020 12:43:29
User entered '8 Aug 2020 07:58'	System	08 Aug 2020 20:35:25

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '187.2' cm	Traci Hull (b) (4)	08 Aug 2020 20:35:25
DataPoint set to visible.	(b) (4) System	08 Aug 2020 13:00:47

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '139.8' kg	Traci Hull (b) (4)	08 Aug 2020 20:35:25
DataPoint set to visible.	(b) (4) System	08 Aug 2020 13:00:47

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '39.89289'	System	16 Sep 2020 23:48:29
User entered '39.9'	System	08 Aug 2020 20:35:25
DataPoint set to visible.	System	08 Aug 2020 13:00:47

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	08 Aug 2020 20:35:25
DataPoint set to visible.	System	08 Aug 2020 13:00:47

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:35:25

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:35:25

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:35:25

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '81'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:35:25

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Aug 2020 20:35:25

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '15'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:35:25

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Aug 2020 20:35:25

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '138'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:35:25

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Aug 2020 20:35:25

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '82'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:35:25

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Aug 2020 20:35:25

US3402284

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:35:44

US3402284

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 22:30:31
Comment added 'SAME DATE'.	Traci Hull (b) (4)	11 Sep 2020 18:34:36
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	11 Sep 2020 18:34:25
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 18:34:25
User entered '08 Aug 2020' reason for change: Data Entry Error	Traci Hull (b) (4)	11 Sep 2020 18:34:25
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	10 Sep 2020 21:06:15
User entered '8 Aug 2020'	Traci Hull (b) (4)	08 Aug 2020 20:35:44

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

[Specify](#)

Audit		User	Time (GMT)
User entered 'CUSTODIAN	(b) (6)	Traci Hull (b) (4)	08 Aug 2020 20:36:40
(b) (6)		(b) (4)	

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '1'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:59

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:40

US3402284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:36:55

US3402284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:44:07
User entered '8 Aug 2020'	Traci Hull (b) (4)	08 Aug 2020 20:36:55

US3402284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:59

[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)	08 Aug 2020 20:36:55

US3402284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:59

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	08 Aug 2020 20:36:55

US3402284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '08 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	08 Aug 2020 12:10:30

US3402284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:59

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 03:03:09
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:03:09
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 12:10:30
User entered '143108' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	08 Aug 2020 12:10:30

US3402284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) 	08 Aug 2020 12:10:30

US3402284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:38:04

US3402284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:38:04

US3402284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:38:04

US3402284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:59

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:38:04

US3402284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:59

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:38:04

US3402284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:51:37
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	02 Nov 2020 13:23:47
User entered 'No (N)'	(b) (4)	02 Nov 2020 13:23:41
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:39:00
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:03:49
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:33:24

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:59

Height

Audit	User	Time (GMT)
User entered '187.2' cm	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:59

Weight

Audit	User	Time (GMT)
User entered '139.8' kg	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:59

Height

Audit	User	Time (GMT)
User entered '187.2' cm	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:59

Weight

Audit	User	Time (GMT)
User entered '139.8' kg	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 20:41:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Aug 2020 20:41:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:41:54
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 20:38:56
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:44:35
User entered '8 Aug 2020' reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 20:41:54
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '07:58' reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 20:41:54
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '08 Aug 2020 07:58'	System	11 Nov 2020 12:44:35
User entered '8 Aug 2020 07:58'	System	08 Aug 2020 20:41:54
User entered empty.	System	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 20:41:54
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 20:41:54
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '81' reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 20:41:54
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Aug 2020 20:41:54
User entered empty.	System	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '15' reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 20:41:54
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Aug 2020 20:41:54
User entered empty.	System	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '138' reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 20:41:54
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Aug 2020 20:41:54
User entered empty.	System	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '82' reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 20:41:54
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:38:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Aug 2020 20:41:54
User entered empty.	System	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:59

Height

Audit	User	Time (GMT)
User entered '187.2' cm	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:59

Weight

Audit	User	Time (GMT)
User entered '139.8' kg	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 20:41:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Aug 2020 20:41:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:41:54
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Aug 2020 20:38:56
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:38:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:45:02
User entered '8 Aug 2020' reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 20:41:54
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

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 14:21:59
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 MINUTES' (Site from System).	Traci Hull (b) (4)	08 Aug 2020 20:42:04
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	08 Aug 2020 20:41:54
User entered '09:25' reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 20:41:54
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	08 Aug 2020 20:38:56
	(b) (4)	

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '08 Aug 2020 09:25'	System	11 Nov 2020 12:45:02
User entered '8 Aug 2020 09:25'	System	08 Aug 2020 20:41:54
User entered empty.	System	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 20:41:54
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 20:41:54
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '85' reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 20:41:54
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Aug 2020 20:41:54
User entered empty.	System	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '15' reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 20:41:54
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:38:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Aug 2020 20:41:54
User entered empty.	System	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '138' reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 20:41:54
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Aug 2020 20:41:54
User entered empty.	System	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '82' reason for change: Data Entry Error	Traci Hull (b) (4)	08 Aug 2020 20:41:54
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Aug 2020 20:41:54
User entered empty.	System	08 Aug 2020 20:38:56

US3402284

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:39:51

US3402284

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:45:15
User entered '8 Aug 2020'	Traci Hull (b) (4)	08 Aug 2020 20:39:51

US3402284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:01:15

US3402284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:01:15

US3402284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

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)	08 Aug 2020 13:01:15

US3402284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	08 Aug 2020 13:01:15

US3402284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 12:45:30
User entered '8 Aug 2020'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:01:15

US3402284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '08:53'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:01:15

US3402284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '08 Aug 2020 08:53'	System	11 Nov 2020 12:45:30
User entered '8 Aug 2020 08:53'	System	08 Aug 2020 13:01:15

US3402284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Abigail Wine (b) (4) (b) (4)	08 Aug 2020 13:01:15

US3402284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	08 Aug 2020 13:01:15

US3402284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	08 Aug 2020 13:01:15

US3402284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:42:29

US3402284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:45:45
User entered '8 Aug 2020'	Traci Hull (b) (4)	08 Aug 2020 20:42:29

US3402284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '08:21'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:42:29

US3402284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '08 Aug 2020 08:21'	System	11 Nov 2020 12:45:45
User entered '8 Aug 2020 08:21'	System	08 Aug 2020 20:42:29

US3402284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:25:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:46:01
User entered '8 Aug 2020'	Traci Hull (b) (4)	08 Aug 2020 20:42:51

US3402284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:59

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:42:51

US3402284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:42:51

US3402284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '08:10'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:42:51

US3402284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '08 Aug 2020 08:10'	System	11 Nov 2020 12:46:01
User entered '8 Aug 2020 08:10'	System	08 Aug 2020 20:42:51

US3402284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:59

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:42:51

US3402284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:42:51

US3402284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:42:51

US3402284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	System	08 Aug 2020 20:42:51

US3402284

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:42:56

US3402284

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:42:56

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:17:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8ac95e62-828c-4ced-be57-3cc7c59907e9'	System	08 Aug 2020 13:18:37
User entered 'Yes (Y)'	System	08 Aug 2020 13:18:37

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:18:08', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8ac95e62-828c-4ced-be57-3cc7c59907e9'	System	08 Aug 2020 13:18:37
User entered '97.9'	System	08 Aug 2020 13:18:37

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:18:22', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8ac95e62-828c-4ced-be57-3cc7c59907e9'	System	08 Aug 2020 13:18:37
User entered 'No (N)'	System	08 Aug 2020 13:18:37

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:18:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8ac95e62-828c-4ced-be57-3cc7c59907e9'	System	08 Aug 2020 13:18:37
User entered '08 Aug 2020 09:18'	System	08 Aug 2020 13:18:37

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 09:13'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:43'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:09:52', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'dc6fa212-ec4e-40ce-b437-7363c0323101'	System	08 Aug 2020 21:10:29
User entered 'Yes (Y)'	System	08 Aug 2020 21:10:29

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:10:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'dc6fa212-ec4e-40ce-b437-7363c0323101'	System	08 Aug 2020 21:10:29
User entered '97.4'	System	08 Aug 2020 21:10:29

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:10:10', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'dc6fa212-ec4e-40ce-b437-7363c0323101'	System	08 Aug 2020 21:10:29
User entered 'No (N)'	System	08 Aug 2020 21:10:29

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:10:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'dc6fa212-ec4e-40ce-b437-7363c0323101'	System	08 Aug 2020 21:10:29
User entered '08 Aug 2020 17:10'	System	08 Aug 2020 21:10:29

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:38'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 2'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:09:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a265a951-4be7-4e2a-8f83-2f4ad87c0ce2'	System	09 Aug 2020 23:10:11
User entered 'Yes (Y)'	System	09 Aug 2020 23:10:11

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:09:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a265a951-4be7-4e2a-8f83-2f4ad87c0ce2'	System	09 Aug 2020 23:10:11
User entered '98.0'	System	09 Aug 2020 23:10:11

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:09:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a265a951-4be7-4e2a-8f83-2f4ad87c0ce2'	System	09 Aug 2020 23:10:11
User entered 'No (N)'	System	09 Aug 2020 23:10:11

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:10:08', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a265a951-4be7-4e2a-8f83-2f4ad87c0ce2'	System	09 Aug 2020 23:10:11
User entered '09 Aug 2020 19:10'	System	09 Aug 2020 23:10:11

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 3'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:58:09', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f72cb5cb-4d74-446c-93e8-33992b22cd68'	System	10 Aug 2020 22:58:37
User entered 'Yes (Y)'	System	10 Aug 2020 22:58:37

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:58:19', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f72cb5cb-4d74-446c-93e8-33992b22cd68' User entered '97.7'	System	10 Aug 2020 22:58:37
	System	10 Aug 2020 22:58:37

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:58:26', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f72cb5cb-4d74-446c-93e8-33992b22cd68'	System	10 Aug 2020 22:58:37
User entered 'No (N)'	System	10 Aug 2020 22:58:37

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:58:34', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f72cb5cb-4d74-446c-93e8-33992b22cd68'	System	10 Aug 2020 22:58:37
User entered '10 Aug 2020 18:58'	System	10 Aug 2020 22:58:37

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 4'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:12:17', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fda2ea90-cb2c-4651-aa0d-de02a86a382e'	System	11 Aug 2020 21:12:45
User entered 'Yes (Y)'	System	11 Aug 2020 21:12:45

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:12:29', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fda2ea90-cb2c-4651-aa0d-de02a86a382e' User entered '97.6'	System	11 Aug 2020 21:12:45

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:12:35', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fda2ea90-cb2c-4651-aa0d-de02a86a382e'	System	11 Aug 2020 21:12:45
User entered 'No (N)'	System	11 Aug 2020 21:12:45

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:12:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fda2ea90-cb2c-4651-aa0d-de02a86a382e'	System	11 Aug 2020 21:12:45
User entered '11 Aug 2020 17:12'	System	11 Aug 2020 21:12:45

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 5'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:40:18', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '51a71c85-ed3e-44d5-9207-1b78583906d0'	System	12 Aug 2020 22:40:48
User entered 'Yes (Y)'	System	12 Aug 2020 22:40:48

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:40:29', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '51a71c85-ed3e-44d5-9207-1b78583906d0'	System	12 Aug 2020 22:40:48
User entered '96.7'	System	12 Aug 2020 22:40:48

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:40:39', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '51a71c85-ed3e-44d5-9207-1b78583906d0'	System	12 Aug 2020 22:40:48
User entered 'No (N)'	System	12 Aug 2020 22:40:48

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:40:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '51a71c85-ed3e-44d5-9207-1b78583906d0'	System	12 Aug 2020 22:40:48
User entered '12 Aug 2020 18:40'	System	12 Aug 2020 22:40:48

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 6'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:48:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'ad48b303-793e-4718-a36a-3b2775ba07db'	System	13 Aug 2020 23:48:53
User entered 'Yes (Y)'	System	13 Aug 2020 23:48:53

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:48:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'ad48b303-793e-4718-a36a-3b2775ba07db' User entered '97.2'	System	13 Aug 2020 23:48:53
	System	13 Aug 2020 23:48:53

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:48:47', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'ad48b303-793e-4718-a36a-3b2775ba07db'	System	13 Aug 2020 23:48:53
User entered 'No (N)'	System	13 Aug 2020 23:48:53

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:48:51', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'ad48b303-793e-4718-a36a-3b2775ba07db'	System	13 Aug 2020 23:48:53
User entered '13 Aug 2020 19:48'	System	13 Aug 2020 23:48:53

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 7'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:29:21', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b962156b-c461-4087-9918-c0997d904a92'	System	15 Aug 2020 00:29:45
User entered 'Yes (Y)'	System	15 Aug 2020 00:29:45

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:29:31', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b962156b-c461-4087-9918-c0997d904a92'	System	15 Aug 2020 00:29:45
User entered '97.7'	System	15 Aug 2020 00:29:45

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:29:38', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b962156b-c461-4087-9918-c0997d904a92'	System	15 Aug 2020 00:29:45
User entered 'No (N)'	System	15 Aug 2020 00:29:45

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:29:43', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b962156b-c461-4087-9918-c0997d904a92'	System	15 Aug 2020 00:29:45
User entered '14 Aug 2020 20:29'	System	15 Aug 2020 00:29:45

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:16:25', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '731eff9c-0697-4ef1-82d7-06326d4ba940'	System	08 Aug 2020 13:17:04
User entered 'None (1)'	System	08 Aug 2020 13:17:04

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:16:39', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '731eff9c-0697-4ef1-82d7-06326d4ba940'	System	08 Aug 2020 13:17:04
User entered 'No (N)'	System	08 Aug 2020 13:17:04

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:16:45', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '731eff9c-0697-4ef1-82d7-06326d4ba940'	System	08 Aug 2020 13:17:04
User entered 'No (N)'	System	08 Aug 2020 13:17:04

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:16:54', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '731eff9c-0697-4ef1-82d7-06326d4ba940'	System	08 Aug 2020 13:17:04
User entered 'None (1)'	System	08 Aug 2020 13:17:04

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:17:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '731eff9c-0697-4ef1-82d7-06326d4ba940'	System	08 Aug 2020 13:17:04
User entered '08 Aug 2020 09:17'	System	08 Aug 2020 13:17:04

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 09:13'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:43'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:10:54', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c38dced4-ebff-4314-9f69-54d5d68a543b'	System	08 Aug 2020 21:11:35
User entered 'None (1)'	System	08 Aug 2020 21:11:35

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:10:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c38dced4-ebff-4314-9f69-54d5d68a543b'	System	08 Aug 2020 21:11:35
User entered 'No (N)'	System	08 Aug 2020 21:11:35

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:11:06', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c38dced4-ebff-4314-9f69-54d5d68a543b'	System	08 Aug 2020 21:11:35
User entered 'No (N)'	System	08 Aug 2020 21:11:35

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:11:20', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c38dced4-ebff-4314-9f69-54d5d68a543b'	System	08 Aug 2020 21:11:35
User entered 'None (1)'	System	08 Aug 2020 21:11:35

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:11:32', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c38dced4-ebff-4314-9f69-54d5d68a543b'	System	08 Aug 2020 21:11:35
User entered '08 Aug 2020 17:11'	System	08 Aug 2020 21:11:35

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:38'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 2'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:10:23', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d4b641d-c8f6-4931-98a2-6ec934fa4c1c'	System	09 Aug 2020 23:10:57
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 23:10:57

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:10:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d4b641d-c8f6-4931-98a2-6ec934fa4c1c'	System	09 Aug 2020 23:10:57
User entered 'No (N)'	System	09 Aug 2020 23:10:57

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:10:37', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d4b641d-c8f6-4931-98a2-6ec934fa4c1c'	System	09 Aug 2020 23:10:57
User entered 'No (N)'	System	09 Aug 2020 23:10:57

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:10:48', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d4b641d-c8f6-4931-98a2-6ec934fa4c1c'	System	09 Aug 2020 23:10:57
User entered 'None (1)'	System	09 Aug 2020 23:10:57

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:10:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d4b641d-c8f6-4931-98a2-6ec934fa4c1c'	System	09 Aug 2020 23:10:57
User entered '09 Aug 2020 19:10'	System	09 Aug 2020 23:10:57

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 3'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:58:44', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fc5d490a-6d2d-4ad4-b741-3cbc0317f9dc'	System	10 Aug 2020 22:59:15
User entered 'Does not interfere with activity (2)'	System	10 Aug 2020 22:59:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:58:49', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fc5d490a-6d2d-4ad4-b741-3cbc0317f9dc'	System	10 Aug 2020 22:59:15
User entered 'No (N)'	System	10 Aug 2020 22:59:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:58:55', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fc5d490a-6d2d-4ad4-b741-3cbc0317f9dc'	System	10 Aug 2020 22:59:15
User entered 'No (N)'	System	10 Aug 2020 22:59:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:07', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fc5d490a-6d2d-4ad4-b741-3cbc0317f9dc'	System	10 Aug 2020 22:59:15
User entered 'None (1)'	System	10 Aug 2020 22:59:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:13', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fc5d490a-6d2d-4ad4-b741-3cbc0317f9dc'	System	10 Aug 2020 22:59:15
User entered '10 Aug 2020 18:59'	System	10 Aug 2020 22:59:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 4'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:12:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58ffad5f-8580-40f6-b656-bf7bad9e1b0a'	System	11 Aug 2020 21:13:20
User entered 'None (1)'	System	11 Aug 2020 21:13:20

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:12:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58ffad5f-8580-40f6-b656-bf7bad9e1b0a'	System	11 Aug 2020 21:13:20
User entered 'No (N)'	System	11 Aug 2020 21:13:20

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58ffad5f-8580-40f6-b656-bf7bad9e1b0a'	System	11 Aug 2020 21:13:20
User entered 'No (N)'	System	11 Aug 2020 21:13:20

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:11', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58ffad5f-8580-40f6-b656-bf7bad9e1b0a'	System	11 Aug 2020 21:13:20
User entered 'None (1)'	System	11 Aug 2020 21:13:20

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:16', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58ffad5f-8580-40f6-b656-bf7bad9e1b0a'	System	11 Aug 2020 21:13:20
User entered '11 Aug 2020 17:13'	System	11 Aug 2020 21:13:20

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 5'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:40:55', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd684b85a-8502-47dc-a706-881196c62280'	System	12 Aug 2020 22:41:19
User entered 'None (1)'	System	12 Aug 2020 22:41:19

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:40:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd684b85a-8502-47dc-a706-881196c62280'	System	12 Aug 2020 22:41:19
User entered 'No (N)'	System	12 Aug 2020 22:41:19

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd684b85a-8502-47dc-a706-881196c62280'	System	12 Aug 2020 22:41:19
User entered 'No (N)'	System	12 Aug 2020 22:41:19

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:11', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd684b85a-8502-47dc-a706-881196c62280'	System	12 Aug 2020 22:41:19
User entered 'None (1)'	System	12 Aug 2020 22:41:19

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:15', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd684b85a-8502-47dc-a706-881196c62280'	System	12 Aug 2020 22:41:19
User entered '12 Aug 2020 18:41'	System	12 Aug 2020 22:41:19

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 6'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:04', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '03c452d9-3170-47b0-a41e-421133cec6db'	System	13 Aug 2020 23:49:28
User entered 'None (1)'	System	13 Aug 2020 23:49:28

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:09', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '03c452d9-3170-47b0-a41e-421133cec6db'	System	13 Aug 2020 23:49:28
User entered 'No (N)'	System	13 Aug 2020 23:49:28

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:14', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '03c452d9-3170-47b0-a41e-421133cec6db'	System	13 Aug 2020 23:49:28
User entered 'No (N)'	System	13 Aug 2020 23:49:28

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:22', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '03c452d9-3170-47b0-a41e-421133cec6db'	System	13 Aug 2020 23:49:28
User entered 'None (1)'	System	13 Aug 2020 23:49:28

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:26', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '03c452d9-3170-47b0-a41e-421133cec6db'	System	13 Aug 2020 23:49:28
User entered '13 Aug 2020 19:49'	System	13 Aug 2020 23:49:28

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 7'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:29:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16abdb91-d09e-4478-8c65-d75693200a2a'	System	15 Aug 2020 00:30:24
User entered 'None (1)'	System	15 Aug 2020 00:30:24

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16abdb91-d09e-4478-8c65-d75693200a2a'	System	15 Aug 2020 00:30:24
User entered 'No (N)'	System	15 Aug 2020 00:30:24

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:11', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16abdb91-d09e-4478-8c65-d75693200a2a'	System	15 Aug 2020 00:30:24
User entered 'No (N)'	System	15 Aug 2020 00:30:24

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:17', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16abdb91-d09e-4478-8c65-d75693200a2a'	System	15 Aug 2020 00:30:24
User entered 'None (1)'	System	15 Aug 2020 00:30:24

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:21', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16abdb91-d09e-4478-8c65-d75693200a2a'	System	15 Aug 2020 00:30:24
User entered '14 Aug 2020 20:30'	System	15 Aug 2020 00:30:24

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:15:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bbd407ef-3752-4d5b-82ad-e90c635f914e'	System	08 Aug 2020 13:16:13
User entered 'None (0)'	System	08 Aug 2020 13:16:13

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:15:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bbd407ef-3752-4d5b-82ad-e90c635f914e'	System	08 Aug 2020 13:16:13
User entered 'None (0)'	System	08 Aug 2020 13:16:13

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:15:17', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bbd407ef-3752-4d5b-82ad-e90c635f914e'	System	08 Aug 2020 13:16:13
User entered 'None (0)'	System	08 Aug 2020 13:16:13

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:15:22', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bbd407ef-3752-4d5b-82ad-e90c635f914e'	System	08 Aug 2020 13:16:13
User entered 'None (0)'	System	08 Aug 2020 13:16:13

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:15:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bbd407ef-3752-4d5b-82ad-e90c635f914e'	System	08 Aug 2020 13:16:13
User entered 'None (0)'	System	08 Aug 2020 13:16:13

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:15:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bbd407ef-3752-4d5b-82ad-e90c635f914e'	System	08 Aug 2020 13:16:13
User entered 'None (0)'	System	08 Aug 2020 13:16:13

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:15:53', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bbd407ef-3752-4d5b-82ad-e90c635f914e'	System	08 Aug 2020 13:16:13
User entered 'No (N)'	System	08 Aug 2020 13:16:13

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:16:11', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bbd407ef-3752-4d5b-82ad-e90c635f914e'	System	08 Aug 2020 13:16:13
User entered '08 Aug 2020 09:16'	System	08 Aug 2020 13:16:13

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 09:13'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:43'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:11:51', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fb13249b-b76c-40aa-81a1-cea942fb5b38'	System	08 Aug 2020 21:12:56
User entered 'None (0)'	System	08 Aug 2020 21:12:56

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:12:10', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fb13249b-b76c-40aa-81a1-cea942fb5b38'	System	08 Aug 2020 21:12:56
User entered 'No interference with activity (1)'	System	08 Aug 2020 21:12:56

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:12:20', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fb13249b-b76c-40aa-81a1-cea942fb5b38'	System	08 Aug 2020 21:12:56
User entered 'No interference with activity (1)'	System	08 Aug 2020 21:12:56

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:12:32', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fb13249b-b76c-40aa-81a1-cea942fb5b38'	System	08 Aug 2020 21:12:56
User entered 'No interference with activity (1)'	System	08 Aug 2020 21:12:56

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:12:36', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fb13249b-b76c-40aa-81a1-cea942fb5b38'	System	08 Aug 2020 21:12:56
User entered 'None (0)'	System	08 Aug 2020 21:12:56

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:12:42', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fb13249b-b76c-40aa-81a1-cea942fb5b38'	System	08 Aug 2020 21:12:56
User entered 'None (0)'	System	08 Aug 2020 21:12:56

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:12:49', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fb13249b-b76c-40aa-81a1-cea942fb5b38'	System	08 Aug 2020 21:12:56
User entered 'No (N)'	System	08 Aug 2020 21:12:56

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:12:54', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fb13249b-b76c-40aa-81a1-cea942fb5b38'	System	08 Aug 2020 21:12:56
User entered '08 Aug 2020 17:12'	System	08 Aug 2020 21:12:56

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:38'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 2'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:11:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e619190-a0a8-4525-91e5-06fbd78735ca'	System	09 Aug 2020 23:11:43
User entered 'None (0)'	System	09 Aug 2020 23:11:43

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:11:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e619190-a0a8-4525-91e5-06fbd78735ca'	System	09 Aug 2020 23:11:43
User entered 'No interference with activity (1)'	System	09 Aug 2020 23:11:43

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:11:18', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e619190-a0a8-4525-91e5-06fbd78735ca'	System	09 Aug 2020 23:11:43
User entered 'No interference with activity (1)'	System	09 Aug 2020 23:11:43

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:11:23', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e619190-a0a8-4525-91e5-06fbd78735ca'	System	09 Aug 2020 23:11:43
User entered 'No interference with activity (1)'	System	09 Aug 2020 23:11:43

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:11:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e619190-a0a8-4525-91e5-06fbd78735ca'	System	09 Aug 2020 23:11:43
User entered 'None (0)'	System	09 Aug 2020 23:11:43

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:11:31', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e619190-a0a8-4525-91e5-06fbd78735ca'	System	09 Aug 2020 23:11:43
User entered 'None (0)'	System	09 Aug 2020 23:11:43

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:11:38', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e619190-a0a8-4525-91e5-06fbd78735ca'	System	09 Aug 2020 23:11:43
User entered 'No (N)'	System	09 Aug 2020 23:11:43

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:11:42', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e619190-a0a8-4525-91e5-06fbd78735ca' User entered '09 Aug 2020 19:11'	System	09 Aug 2020 23:11:43
	System	09 Aug 2020 23:11:43

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 3'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:26', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'caa87b47-cb44-4d5a-9f73-dc36fe521f1e'	System	10 Aug 2020 23:00:02
User entered 'None (0)'	System	10 Aug 2020 23:00:02

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:31', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'caa87b47-cb44-4d5a-9f73-dc36fe521f1e'	System	10 Aug 2020 23:00:02
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:00:02

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:35', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'caa87b47-cb44-4d5a-9f73-dc36fe521f1e'	System	10 Aug 2020 23:00:02
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:00:02

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'caa87b47-cb44-4d5a-9f73-dc36fe521f1e'	System	10 Aug 2020 23:00:02
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:00:02

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:45', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'caa87b47-cb44-4d5a-9f73-dc36fe521f1e'	System	10 Aug 2020 23:00:02
User entered 'None (0)'	System	10 Aug 2020 23:00:02

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:48', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'caa87b47-cb44-4d5a-9f73-dc36fe521f1e'	System	10 Aug 2020 23:00:02
User entered 'None (0)'	System	10 Aug 2020 23:00:02

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:55', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'caa87b47-cb44-4d5a-9f73-dc36fe521f1e'	System	10 Aug 2020 23:00:02
User entered 'No (N)'	System	10 Aug 2020 23:00:02

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'caa87b47-cb44-4d5a-9f73-dc36fe521f1e'	System	10 Aug 2020 23:00:02
User entered '10 Aug 2020 18:59'	System	10 Aug 2020 23:00:02

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 4'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '38b12010-85d7-405a-857f-2a54d0ad14c0'	System	11 Aug 2020 21:14:04
User entered 'None (0)'	System	11 Aug 2020 21:14:04

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:32', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '38b12010-85d7-405a-857f-2a54d0ad14c0'	System	11 Aug 2020 21:14:04
User entered 'No interference with activity (1)'	System	11 Aug 2020 21:14:04

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:36', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '38b12010-85d7-405a-857f-2a54d0ad14c0'	System	11 Aug 2020 21:14:04
User entered 'No interference with activity (1)'	System	11 Aug 2020 21:14:04

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '38b12010-85d7-405a-857f-2a54d0ad14c0'	System	11 Aug 2020 21:14:04
User entered 'No interference with activity (1)'	System	11 Aug 2020 21:14:04

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:45', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '38b12010-85d7-405a-857f-2a54d0ad14c0'	System	11 Aug 2020 21:14:04
User entered 'None (0)'	System	11 Aug 2020 21:14:04

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:48', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '38b12010-85d7-405a-857f-2a54d0ad14c0'	System	11 Aug 2020 21:14:04
User entered 'None (0)'	System	11 Aug 2020 21:14:04

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:54', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '38b12010-85d7-405a-857f-2a54d0ad14c0'	System	11 Aug 2020 21:14:04
User entered 'No (N)'	System	11 Aug 2020 21:14:04

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:57', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '38b12010-85d7-405a-857f-2a54d0ad14c0'	System	11 Aug 2020 21:14:04
User entered '11 Aug 2020 17:13'	System	11 Aug 2020 21:14:04

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 5'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:26', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aa798807-54db-423d-a2cc-c9493ea7680e'	System	12 Aug 2020 22:42:02
User entered 'None (0)'	System	12 Aug 2020 22:42:02

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:31', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aa798807-54db-423d-a2cc-c9493ea7680e'	System	12 Aug 2020 22:42:02
User entered 'No interference with activity (1)'	System	12 Aug 2020 22:42:02

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:36', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aa798807-54db-423d-a2cc-c9493ea7680e'	System	12 Aug 2020 22:42:02
User entered 'No interference with activity (1)'	System	12 Aug 2020 22:42:02

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:39', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aa798807-54db-423d-a2cc-c9493ea7680e'	System	12 Aug 2020 22:42:02
User entered 'No interference with activity (1)'	System	12 Aug 2020 22:42:02

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:43', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aa798807-54db-423d-a2cc-c9493ea7680e'	System	12 Aug 2020 22:42:02
User entered 'None (0)'	System	12 Aug 2020 22:42:02

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:47', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aa798807-54db-423d-a2cc-c9493ea7680e'	System	12 Aug 2020 22:42:02
User entered 'None (0)'	System	12 Aug 2020 22:42:02

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aa798807-54db-423d-a2cc-c9493ea7680e'	System	12 Aug 2020 22:42:02
User entered 'No (N)'	System	12 Aug 2020 22:42:02

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aa798807-54db-423d-a2cc-c9493ea7680e'	System	12 Aug 2020 22:42:02
User entered '12 Aug 2020 18:41'	System	12 Aug 2020 22:42:02

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 6'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:34', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5a602974-6ad4-4e7a-bb2e-822a970a6393'	System	13 Aug 2020 23:50:13
User entered 'None (0)'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:42', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5a602974-6ad4-4e7a-bb2e-822a970a6393'	System	13 Aug 2020 23:50:13
User entered 'No interference with activity (1)'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5a602974-6ad4-4e7a-bb2e-822a970a6393'	System	13 Aug 2020 23:50:13
User entered 'No interference with activity (1)'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:51', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5a602974-6ad4-4e7a-bb2e-822a970a6393'	System	13 Aug 2020 23:50:13
User entered 'No interference with activity (1)'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:55', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5a602974-6ad4-4e7a-bb2e-822a970a6393'	System	13 Aug 2020 23:50:13
User entered 'None (0)'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:58', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5a602974-6ad4-4e7a-bb2e-822a970a6393'	System	13 Aug 2020 23:50:13
User entered 'None (0)'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:50:06', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5a602974-6ad4-4e7a-bb2e-822a970a6393'	System	13 Aug 2020 23:50:13
User entered 'No (N)'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:50:10', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5a602974-6ad4-4e7a-bb2e-822a970a6393'	System	13 Aug 2020 23:50:13
User entered '13 Aug 2020 19:50'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 7'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd36aec1d-ba60-45de-96e6-9f747a4deb54'	System	15 Aug 2020 00:31:09
User entered 'None (0)'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:36', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd36aec1d-ba60-45de-96e6-9f747a4deb54'	System	15 Aug 2020 00:31:09
User entered 'No interference with activity (1)'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:42', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd36aec1d-ba60-45de-96e6-9f747a4deb54'	System	15 Aug 2020 00:31:09
User entered 'No interference with activity (1)'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd36aec1d-ba60-45de-96e6-9f747a4deb54'	System	15 Aug 2020 00:31:09
User entered 'No interference with activity (1)'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd36aec1d-ba60-45de-96e6-9f747a4deb54'	System	15 Aug 2020 00:31:09
User entered 'None (0)'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:54', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd36aec1d-ba60-45de-96e6-9f747a4deb54'	System	15 Aug 2020 00:31:09
User entered 'None (0)'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:31:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd36aec1d-ba60-45de-96e6-9f747a4deb54'	System	15 Aug 2020 00:31:09
User entered 'No (N)'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:31:04', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd36aec1d-ba60-45de-96e6-9f747a4deb54'	System	15 Aug 2020 00:31:09
User entered '14 Aug 2020 20:31'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:50:13
User entered 'Day 8'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-15T22:49:20', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c121a01a-1d5d-4886-af52-c7c4dec7d669'	System	16 Aug 2020 02:49:37
User entered 'No interference with activity (1)'	System	16 Aug 2020 02:49:37

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-15T22:49:32', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c121a01a-1d5d-4886-af52-c7c4dec7d669'	System	16 Aug 2020 02:49:37
User entered '15 Aug 2020 22:49'	System	16 Aug 2020 02:49:37

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 00:31:09
User entered 'Day 9'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-16T19:17:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8ed4d51e-2a7e-4a6c-b781-720f6f5e9e67'	System	16 Aug 2020 23:17:25
User entered 'No interference with activity (1)'	System	16 Aug 2020 23:17:25

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-16T19:17:24', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8ed4d51e-2a7e-4a6c-b781-720f6f5e9e67'	System	16 Aug 2020 23:17:25
User entered '16 Aug 2020 19:17'	System	16 Aug 2020 23:17:25

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 02:49:37
User entered 'Day 10'	System	16 Aug 2020 02:49:37

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-17T17:47:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '235dad20-4f87-40b5-8ce6-070e54680360'	System	17 Aug 2020 21:47:52
User entered 'Some interference with activity (2)'	System	17 Aug 2020 21:47:52

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-17T17:47:47', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '235dad20-4f87-40b5-8ce6-070e54680360'	System	17 Aug 2020 21:47:52
User entered '17 Aug 2020 17:47'	System	17 Aug 2020 21:47:52

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 02:49:37

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 02:49:37

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 23:17:25
User entered 'Day 11'	System	16 Aug 2020 23:17:25

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-18T21:09:04', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5ed09058-c479-481e-8ac7-554cb12cde78'	System	19 Aug 2020 01:09:13
User entered 'No interference with activity (1)'	System	19 Aug 2020 01:09:13

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-18T21:09:11', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5ed09058-c479-481e-8ac7-554cb12cde78'	System	19 Aug 2020 01:09:13
User entered '18 Aug 2020 21:09'	System	19 Aug 2020 01:09:13

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 23:17:25

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 23:17:25

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 21:47:52
User entered 'Day 12'	System	17 Aug 2020 21:47:52

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-19T18:52:26', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'eae2f9cd-4a01-4389-8685-22d4da0fc799'	System	19 Aug 2020 22:52:36
User entered 'No interference with activity (1)'	System	19 Aug 2020 22:52:36

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-19T18:52:31', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'eae2f9cd-4a01-4389-8685-22d4da0fc799'	System	19 Aug 2020 22:52:36
User entered '19 Aug 2020 18:52'	System	19 Aug 2020 22:52:36

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 21:47:52

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 21:47:52

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 01:09:13
User entered 'Day 13'	System	19 Aug 2020 01:09:13

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-20T18:42:23', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d4714ef-340b-4ea2-aa25-9d13a1ee104f'	System	20 Aug 2020 22:42:31
User entered 'No interference with activity (1)'	System	20 Aug 2020 22:42:31

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-20T18:42:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d4714ef-340b-4ea2-aa25-9d13a1ee104f'	System	20 Aug 2020 22:42:31
User entered '20 Aug 2020 18:42'	System	20 Aug 2020 22:42:31

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 01:09:13

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 01:09:13

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 22:52:36
User entered 'Day 14'	System	19 Aug 2020 22:52:36

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-21T19:59:34', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '60d2b570-01dd-495a-a2c5-0119ce58844a'	System	21 Aug 2020 23:59:54
User entered 'Some interference with activity (2)'	System	21 Aug 2020 23:59:54

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-21T19:59:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '60d2b570-01dd-495a-a2c5-0119ce58844a'	System	21 Aug 2020 23:59:54
User entered '21 Aug 2020 19:59'	System	21 Aug 2020 23:59:54

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 22:52:36

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 22:52:36

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 22:42:31
User entered 'Day 15'	System	20 Aug 2020 22:42:31

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-22T17:10:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '54edcbf4-1caf-46e9-b52c-b97f5b69442a' User entered 'None (0)'	System	22 Aug 2020 21:11:01

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-22T17:10:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '54edcbf4-1caf-46e9-b52c-b97f5b69442a'	System	22 Aug 2020 21:11:01
User entered '22 Aug 2020 17:10'	System	22 Aug 2020 21:11:01

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 22:42:31

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 22:42:31

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:50:13
User entered 'Day 8'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-15T22:49:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'dfeefc7e-4555-49c2-a4c5-7d1c7a158821'	System	16 Aug 2020 02:49:55
User entered 'No interference with activity (1)'	System	16 Aug 2020 02:49:55

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-15T22:49:53', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'dfeefc7e-4555-49c2-a4c5-7d1c7a158821'	System	16 Aug 2020 02:49:55
User entered '15 Aug 2020 22:49'	System	16 Aug 2020 02:49:55

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 00:31:09
User entered 'Day 9'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-16T19:17:40', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b0148edf-ac3d-435a-88a2-05f55ceba77e'	System	16 Aug 2020 23:17:48
User entered 'No interference with activity (1)'	System	16 Aug 2020 23:17:48

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-16T19:17:44', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b0148edf-ac3d-435a-88a2-05f55ceba77e'	System	16 Aug 2020 23:17:48
User entered '16 Aug 2020 19:17'	System	16 Aug 2020 23:17:48

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 02:49:55
User entered 'Day 10'	System	16 Aug 2020 02:49:55

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-17T17:48:30', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '4f6a62ff-d8a9-4d00-a5b0-ffa5bd6237d5'	System	17 Aug 2020 21:48:38
User entered 'Some interference with activity (2)'	System	17 Aug 2020 21:48:38

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-17T17:48:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '4f6a62ff-d8a9-4d00-a5b0-ffa5bd6237d5'	System	17 Aug 2020 21:48:38
User entered '17 Aug 2020 17:48'	System	17 Aug 2020 21:48:38

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 02:49:55

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 02:49:55

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 23:17:48
User entered 'Day 11'	System	16 Aug 2020 23:17:48

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-18T21:09:19', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b6722e0f-f959-4266-a07e-212b75ea834b'	System	19 Aug 2020 01:09:27
User entered 'No interference with activity (1)'	System	19 Aug 2020 01:09:27

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-18T21:09:23', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b6722e0f-f959-4266-a07e-212b75ea834b'	System	19 Aug 2020 01:09:27
User entered '18 Aug 2020 21:09'	System	19 Aug 2020 01:09:27

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 23:17:48

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 23:17:48

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 21:48:38
User entered 'Day 12'	System	17 Aug 2020 21:48:38

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-19T18:52:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '75d09134-8426-41e9-8b3f-7febb89a6a7b'	System	19 Aug 2020 22:52:53
User entered 'No interference with activity (1)'	System	19 Aug 2020 22:52:53

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-19T18:52:49', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '75d09134-8426-41e9-8b3f-7febb89a6a7b'	System	19 Aug 2020 22:52:53
User entered '19 Aug 2020 18:52'	System	19 Aug 2020 22:52:53

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 21:48:38

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 21:48:38

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 01:09:27
User entered 'Day 13'	System	19 Aug 2020 01:09:27

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-20T18:42:37', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '08ffffbd-7e48-43d9-9423-d7a40b64a2ab'	System	20 Aug 2020 22:42:44
User entered 'No interference with activity (1)'	System	20 Aug 2020 22:42:44

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-20T18:42:42', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '08ffffbd-7e48-43d9-9423-d7a40b64a2ab'	System	20 Aug 2020 22:42:44
User entered '20 Aug 2020 18:42'	System	20 Aug 2020 22:42:44

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 01:09:27

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 01:09:27

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 22:52:53
User entered 'Day 14'	System	19 Aug 2020 22:52:53

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-21T19:59:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '98e16756-cfe9-4918-b0c0-d8bec1647eee'	System	22 Aug 2020 00:00:09
User entered 'Some interference with activity (2)'	System	22 Aug 2020 00:00:09

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-21T20:00:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '98e16756-cfe9-4918-b0c0-d8bec1647eee'	System	22 Aug 2020 00:00:09
User entered '21 Aug 2020 20:00'	System	22 Aug 2020 00:00:09

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 22:52:53

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 22:52:53

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 22:42:44
User entered 'Day 15'	System	20 Aug 2020 22:42:44

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-22T17:11:30', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bb533f09-2403-4c7e-974b-1b2d080dcd02'	System	22 Aug 2020 21:11:39
User entered 'None (0)'	System	22 Aug 2020 21:11:39

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-22T17:11:34', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bb533f09-2403-4c7e-974b-1b2d080dcd02'	System	22 Aug 2020 21:11:39
User entered '22 Aug 2020 17:11'	System	22 Aug 2020 21:11:39

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 22:42:44

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 22:42:44

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:50:13
User entered 'Day 8'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-15T22:50:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8b2bdb2c-43a7-4383-9585-65410577095f'	System	16 Aug 2020 02:50:10
User entered 'No interference with activity (1)'	System	16 Aug 2020 02:50:10

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-15T22:50:06', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8b2bdb2c-43a7-4383-9585-65410577095f'	System	16 Aug 2020 02:50:10
User entered '15 Aug 2020 22:50'	System	16 Aug 2020 02:50:10

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 00:31:09
User entered 'Day 9'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-16T19:17:53', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6ea44a54-5985-4940-bbd7-8fa9ddab00bd'	System	16 Aug 2020 23:18:01
User entered 'Some interference with activity (2)'	System	16 Aug 2020 23:18:01

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-16T19:17:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6ea44a54-5985-4940-bbd7-8fa9ddab00bd'	System	16 Aug 2020 23:18:01
User entered '16 Aug 2020 19:17'	System	16 Aug 2020 23:18:01

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 02:50:10
User entered 'Day 10'	System	16 Aug 2020 02:50:10

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-17T17:48:16', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bd1f2a08-a378-4968-88bf-479aa80826b5'	System	17 Aug 2020 21:48:22
User entered 'Some interference with activity (2)'	System	17 Aug 2020 21:48:22

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-17T17:48:20', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bd1f2a08-a378-4968-88bf-479aa80826b5'	System	17 Aug 2020 21:48:22
User entered '17 Aug 2020 17:48'	System	17 Aug 2020 21:48:22

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 02:50:10

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 02:50:10

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 23:18:01
User entered 'Day 11'	System	16 Aug 2020 23:18:01

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-18T21:09:31', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '64970c76-f9a0-4e99-a35e-86007b51d19b'	System	19 Aug 2020 01:09:41
User entered 'No interference with activity (1)'	System	19 Aug 2020 01:09:41

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-18T21:09:37', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '64970c76-f9a0-4e99-a35e-86007b51d19b'	System	19 Aug 2020 01:09:41
User entered '18 Aug 2020 21:09'	System	19 Aug 2020 01:09:41

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 23:18:01

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 23:18:01

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 21:48:22
User entered 'Day 12'	System	17 Aug 2020 21:48:22

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-19T18:53:02', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9a7e36a1-1b12-44bd-a7e6-4c1d8da433b6'	System	19 Aug 2020 22:53:08
User entered 'No interference with activity (1)'	System	19 Aug 2020 22:53:08

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-19T18:53:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9a7e36a1-1b12-44bd-a7e6-4c1d8da433b6'	System	19 Aug 2020 22:53:08
User entered '19 Aug 2020 18:53'	System	19 Aug 2020 22:53:08

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 21:48:22

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 21:48:22

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 01:09:41
User entered 'Day 13'	System	19 Aug 2020 01:09:41

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-20T18:42:51', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '13b43789-1959-457b-9ff5-f1d9131e3f5a'	System	20 Aug 2020 22:42:59
User entered 'None (0)'	System	20 Aug 2020 22:42:59

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-20T18:42:55', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '13b43789-1959-457b-9ff5-f1d9131e3f5a'	System	20 Aug 2020 22:42:59
User entered '20 Aug 2020 18:42'	System	20 Aug 2020 22:42:59

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 01:09:41

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 01:09:41

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Aug 2020 23:50:13
User entered 'Day 8'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-15T22:50:34', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f65a4c69-c580-44fe-8e3c-1a286274fb54'	System	16 Aug 2020 02:50:41
User entered 'No (N)'	System	16 Aug 2020 02:50:41

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-15T22:50:39', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f65a4c69-c580-44fe-8e3c-1a286274fb54'	System	16 Aug 2020 02:50:41
User entered '15 Aug 2020 22:50'	System	16 Aug 2020 02:50:41

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 23:50:13

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Aug 2020 00:31:09
User entered 'Day 9'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-16T19:18:08', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9dd4c99e-b157-44a6-9df2-41a013140346'	System	16 Aug 2020 23:18:13
User entered 'No (N)'	System	16 Aug 2020 23:18:13

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-16T19:18:11', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9dd4c99e-b157-44a6-9df2-41a013140346'	System	16 Aug 2020 23:18:13
User entered '16 Aug 2020 19:18'	System	16 Aug 2020 23:18:13

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	15 Aug 2020 00:31:09

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 02:49:37
User entered 'Day 10'	System	16 Aug 2020 02:49:37

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-17T17:47:58', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fbd487e1-98b0-41ae-ae89-3dc8db7e3869'	System	17 Aug 2020 21:48:05
User entered 'No (N)'	System	17 Aug 2020 21:48:05

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-17T17:48:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fbd487e1-98b0-41ae-ae89-3dc8db7e3869'	System	17 Aug 2020 21:48:05
User entered '17 Aug 2020 17:48'	System	17 Aug 2020 21:48:05

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	16 Aug 2020 02:49:37

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	16 Aug 2020 02:49:37

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Aug 2020 23:17:25
User entered 'Day 11'	System	16 Aug 2020 23:17:25

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-18T21:09:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '100785ff-8b74-42ee-a50a-1953d71cca14'	System	19 Aug 2020 01:09:51
User entered 'No (N)'	System	19 Aug 2020 01:09:51

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-18T21:09:49', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '100785ff-8b74-42ee-a50a-1953d71cca14'	System	19 Aug 2020 01:09:51
User entered '18 Aug 2020 21:09'	System	19 Aug 2020 01:09:51

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	16 Aug 2020 23:17:25

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	16 Aug 2020 23:17:25

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 21:47:52
User entered 'Day 12'	System	17 Aug 2020 21:47:52

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-19T18:53:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '11ae3dbc-d387-47a5-8dc2-8c324f87023e'	System	19 Aug 2020 22:53:19
User entered 'No (N)'	System	19 Aug 2020 22:53:19

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-19T18:53:17', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '11ae3dbc-d387-47a5-8dc2-8c324f87023e'	System	19 Aug 2020 22:53:19
User entered '19 Aug 2020 18:53'	System	19 Aug 2020 22:53:19

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 21:47:52

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 21:47:52

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 01:09:13
User entered 'Day 13'	System	19 Aug 2020 01:09:13

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-20T18:43:02', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '48f2fc3e-d94a-49b8-98fb-d529a8c19fb5'	System	20 Aug 2020 22:43:10
User entered 'No (N)'	System	20 Aug 2020 22:43:10

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-20T18:43:08', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '48f2fc3e-d94a-49b8-98fb-d529a8c19fb5'	System	20 Aug 2020 22:43:10
User entered '20 Aug 2020 18:43'	System	20 Aug 2020 22:43:10

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 01:09:13

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 01:09:13

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 22:52:36
User entered 'Day 14'	System	19 Aug 2020 22:52:36

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-21T20:00:10', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0e8ace33-8de4-4d1b-81fb-a8304b3c8c58'	System	22 Aug 2020 00:00:16
User entered 'No (N)'	System	22 Aug 2020 00:00:16

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-21T20:00:13', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0e8ace33-8de4-4d1b-81fb-a8304b3c8c58'	System	22 Aug 2020 00:00:16
User entered '21 Aug 2020 20:00'	System	22 Aug 2020 00:00:16

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 22:52:36

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 22:52:36

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 22:42:31
User entered 'Day 15'	System	20 Aug 2020 22:42:31

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-22T17:11:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bb5cf396-c67e-4ba4-bae8-98f0a752d436'	System	22 Aug 2020 21:11:46
User entered 'No (N)'	System	22 Aug 2020 21:11:46

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-22T17:11:44', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bb5cf396-c67e-4ba4-bae8-98f0a752d436'	System	22 Aug 2020 21:11:46
User entered '22 Aug 2020 17:11'	System	22 Aug 2020 21:11:46

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 22:42:31

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 22:42:31

US3402284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 18:08:31

US3402284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[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 18:08:31

US3402284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[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 18:08:31

US3402284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Aug 2020 18:08:31

US3402284

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

[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 18:08:36

US3402284

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 18:08:36

US3402284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	24 Aug 2020 18:09:05
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	24 Aug 2020 18:08:54
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 18:08:54

US3402284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '22 Aug 2020' reason for change: Data Entry Error	Traci Hull (b) (4)	24 Aug 2020 18:09:05
User entered empty.	Traci Hull (b) (4)	24 Aug 2020 18:08:54

US3402284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[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 18:08:54

US3402284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Aug 2020 18:08:54

US3402284

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

[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 18:09:14

US3402284

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 18:09:14

US3402284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Aug 2020 15:47:45

US3402284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Traci Hull (b) (4) (b) (4)	29 Aug 2020 15:47:45

US3402284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	29 Aug 2020 15:47:45

US3402284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	29 Aug 2020 15:47:45

US3402284

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	29 Aug 2020 15:47:50

US3402284

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 15:47:50

US3402284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:06:15

US3402284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:06:15

US3402284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:59

[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)	10 Sep 2020 21:06:15

US3402284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:59

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	10 Sep 2020 21:06:15

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '15:36'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:36'	System	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.5' C	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '91'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '15'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '138'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '87'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '16:50'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 16:50'	System	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '87'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '15'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '126'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '80'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 21:09:27

US3402284

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:33

US3402284

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:33

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Abigail Wine (b) (4) (b) (4)	10 Sep 2020 20:20:29

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Abigail Wine (b) (4) (b) (4)	10 Sep 2020 20:20:29

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

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)	10 Sep 2020 20:20:29

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 20:20:29

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Abigail Wine (b) (4) (b) (4)	10 Sep 2020 20:20:29

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '16:17'	Abigail Wine (b) (4) (b) (4)	10 Sep 2020 20:20:29

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 16:17'	System	10 Sep 2020 20:20:29

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Abigail Wine (b) (4) (b) (4)	10 Sep 2020 20:20:29

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	10 Sep 2020 20:20:29

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 20:20:29

US3402284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:53

US3402284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:53

US3402284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '15:52'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:09:53

US3402284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:52'	System	10 Sep 2020 21:09:53

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:25:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:10:09

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:59

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:10:09

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:10:09

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '15:55'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:10:09

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 15:55'	System	10 Sep 2020 21:10:09

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:59

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:10:09

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:10:09

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:10:09

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 21:10:09

US3402284

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	10 Sep 2020 21:10:13

US3402284

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 21:10:13

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:51:34', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6770faa5-a633-4908-b2ad-792dada40d07'	System	10 Sep 2020 20:52:22
User entered 'Yes (Y)'	System	10 Sep 2020 20:52:22

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:51:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6770faa5-a633-4908-b2ad-792dada40d07'	System	10 Sep 2020 20:52:22
User entered '98.2'	System	10 Sep 2020 20:52:22

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:52:06', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6770faa5-a633-4908-b2ad-792dada40d07'	System	10 Sep 2020 20:52:22
User entered 'No (N)'	System	10 Sep 2020 20:52:22

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:52:18', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6770faa5-a633-4908-b2ad-792dada40d07'	System	10 Sep 2020 20:52:22
User entered '10 Sep 2020 16:52'	System	10 Sep 2020 20:52:22

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 16:37'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 19:07'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:29:02', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0da8c531-583d-4f82-b4f1-7462fba11e6d'	System	11 Sep 2020 01:29:45
User entered 'Yes (Y)'	System	11 Sep 2020 01:29:45

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:29:11', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0da8c531-583d-4f82-b4f1-7462fba11e6d'	System	11 Sep 2020 01:29:45
User entered '98.2'	System	11 Sep 2020 01:29:45

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:29:30', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0da8c531-583d-4f82-b4f1-7462fba11e6d'	System	11 Sep 2020 01:29:45
User entered 'No (N)'	System	11 Sep 2020 01:29:45

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:29:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0da8c531-583d-4f82-b4f1-7462fba11e6d'	System	11 Sep 2020 01:29:45
User entered '10 Sep 2020 21:29'	System	11 Sep 2020 01:29:45

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 20:02'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 2'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:53:31', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '682f6c0b-7d7f-4f20-bc3d-7dc848cd889d'	System	11 Sep 2020 23:53:56
User entered 'Yes (Y)'	System	11 Sep 2020 23:53:56

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:53:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '682f6c0b-7d7f-4f20-bc3d-7dc848cd889d'	System	11 Sep 2020 23:53:56
User entered '97.7'	System	11 Sep 2020 23:53:56

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:53:48', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '682f6c0b-7d7f-4f20-bc3d-7dc848cd889d'	System	11 Sep 2020 23:53:56
User entered 'No (N)'	System	11 Sep 2020 23:53:56

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:53:52', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '682f6c0b-7d7f-4f20-bc3d-7dc848cd889d'	System	11 Sep 2020 23:53:56
User entered '11 Sep 2020 19:53'	System	11 Sep 2020 23:53:56

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 3'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:07:30', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '152c84ad-c5ef-4823-8652-716f0beffb88'	System	12 Sep 2020 23:08:11
User entered 'Yes (Y)'	System	12 Sep 2020 23:08:11

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:07:38', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '152c84ad-c5ef-4823-8652-716f0beffb88'	System	12 Sep 2020 23:08:11
User entered '98.7'	System	12 Sep 2020 23:08:11

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:07:45', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '152c84ad-c5ef-4823-8652-716f0beffb88'	System	12 Sep 2020 23:08:11
User entered 'No (N)'	System	12 Sep 2020 23:08:11

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:07:49', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '152c84ad-c5ef-4823-8652-716f0beffb88'	System	12 Sep 2020 23:08:11
User entered '12 Sep 2020 19:07'	System	12 Sep 2020 23:08:11

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 4'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:32:21', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'ef676004-45e6-4cde-a1fd-a2edb09606f3'	System	14 Sep 2020 00:32:33
User entered 'Yes (Y)'	System	14 Sep 2020 00:32:33

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:32:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'ef676004-45e6-4cde-a1fd-a2edb09606f3'	System	14 Sep 2020 00:32:33
User entered '98.8'	System	14 Sep 2020 00:32:33

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:32:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'ef676004-45e6-4cde-a1fd-a2edb09606f3'	System	14 Sep 2020 00:32:33
User entered 'No (N)'	System	14 Sep 2020 00:32:33

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:32:29', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'ef676004-45e6-4cde-a1fd-a2edb09606f3'	System	14 Sep 2020 00:32:33
User entered '13 Sep 2020 20:32'	System	14 Sep 2020 00:32:33

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 5'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:52:34', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a3359203-fabb-4e9c-a406-3a71282d2446'	System	14 Sep 2020 23:53:17
User entered 'Yes (Y)'	System	14 Sep 2020 23:53:17

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:52:49', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a3359203-fabb-4e9c-a406-3a71282d2446'	System	14 Sep 2020 23:53:17
User entered '98.4'	System	14 Sep 2020 23:53:17

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:52:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a3359203-fabb-4e9c-a406-3a71282d2446'	System	14 Sep 2020 23:53:17
User entered 'Yes (Y)'	System	14 Sep 2020 23:53:17

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:59

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 'MILD FATIGUE, MUSCLE ACCHEs' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 11:21:41
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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:08', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a3359203-fabb-4e9c-a406-3a71282d2446'	Tammy Kohn (b) (4)	26 Sep 2020 15:14:35
User entered '1'	System	14 Sep 2020 23:53:17
	System	14 Sep 2020 23:53:17
	System	14 Sep 2020 23:53:17

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:08', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a3359203-fabb-4e9c-a406-3a71282d2446'	System	14 Sep 2020 23:53:17
User entered '0'	System	14 Sep 2020 23:53:17

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:15', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a3359203-fabb-4e9c-a406-3a71282d2446'	System	14 Sep 2020 23:53:17
User entered '14 Sep 2020 19:53'	System	14 Sep 2020 23:53:17

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 6'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:32:47', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '25329765-d454-4f66-8dec-4e9f16519a7a' User entered 'Yes (Y)'	System	15 Sep 2020 23:33:26
	System	15 Sep 2020 23:33:26

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:32:57', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '25329765-d454-4f66-8dec-4e9f16519a7a' User entered '97.6'	System	15 Sep 2020 23:33:26

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:33:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '25329765-d454-4f66-8dec-4e9f16519a7a'	System	15 Sep 2020 23:33:26
User entered 'Yes (Y)'	System	15 Sep 2020 23:33:26

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:59

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 'MILD FATIGUE, MUSCLE ACHES AND JOINT PAIN' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 11:21:30
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).	Tammy Kohn (b) (4)	26 Sep 2020 15:15:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:33:17', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '25329765-d454-4f66-8dec-4e9f16519a7a'	System	15 Sep 2020 23:33:26
User entered '1'	System	15 Sep 2020 23:33:26

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:33:17', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '25329765-d454-4f66-8dec-4e9f16519a7a' User entered '0'	System	15 Sep 2020 23:33:26
	System	15 Sep 2020 23:33:26

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:33:23', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '25329765-d454-4f66-8dec-4e9f16519a7a'	System	15 Sep 2020 23:33:26
User entered '15 Sep 2020 19:33'	System	15 Sep 2020 23:33:26

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 7'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:03:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f8e0cb44-3a28-4d8c-be04-5e48a1c02cda'	System	17 Sep 2020 00:04:18
User entered 'Yes (Y)'	System	17 Sep 2020 00:04:18

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:04:04', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f8e0cb44-3a28-4d8c-be04-5e48a1c02cda'	System	17 Sep 2020 00:04:18
User entered '97.6'	System	17 Sep 2020 00:04:18

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:04:10', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f8e0cb44-3a28-4d8c-be04-5e48a1c02cda'	System	17 Sep 2020 00:04:18
User entered 'No (N)'	System	17 Sep 2020 00:04:18

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:04:15', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f8e0cb44-3a28-4d8c-be04-5e48a1c02cda'	System	17 Sep 2020 00:04:18
User entered '16 Sep 2020 20:04'	System	17 Sep 2020 00:04:18

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:52:34', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '84860adb-da16-41e4-94e2-7804756f10d1'	System	10 Sep 2020 20:53:20
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 20:53:20

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:02', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '84860adb-da16-41e4-94e2-7804756f10d1'	System	10 Sep 2020 20:53:20
User entered 'No (N)'	System	10 Sep 2020 20:53:20

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:06', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '84860adb-da16-41e4-94e2-7804756f10d1'	System	10 Sep 2020 20:53:20
User entered 'No (N)'	System	10 Sep 2020 20:53:20

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:15', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '84860adb-da16-41e4-94e2-7804756f10d1'	System	10 Sep 2020 20:53:20
User entered 'None (1)'	System	10 Sep 2020 20:53:20

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:19', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '84860adb-da16-41e4-94e2-7804756f10d1'	System	10 Sep 2020 20:53:20
User entered '10 Sep 2020 16:53'	System	10 Sep 2020 20:53:20

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 16:37'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 19:07'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:29:52', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '80f168d0-9c15-43e8-8b45-aa3021e573e0'	System	11 Sep 2020 01:30:21
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 01:30:21

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:29:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '80f168d0-9c15-43e8-8b45-aa3021e573e0'	System	11 Sep 2020 01:30:21
User entered 'No (N)'	System	11 Sep 2020 01:30:21

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:30:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '80f168d0-9c15-43e8-8b45-aa3021e573e0'	System	11 Sep 2020 01:30:21
User entered 'No (N)'	System	11 Sep 2020 01:30:21

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:30:13', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '80f168d0-9c15-43e8-8b45-aa3021e573e0'	System	11 Sep 2020 01:30:21
User entered 'None (1)'	System	11 Sep 2020 01:30:21

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:30:16', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '80f168d0-9c15-43e8-8b45-aa3021e573e0'	System	11 Sep 2020 01:30:21
User entered '10 Sep 2020 21:30'	System	11 Sep 2020 01:30:21

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 20:02'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 2'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '54d4e31a-e951-4b64-aff8-cacfc993284b'	System	11 Sep 2020 23:54:26
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 23:54:26

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '54d4e31a-e951-4b64-aff8-cacfc993284b' User entered 'No (N)'	System	11 Sep 2020 23:54:26
	System	11 Sep 2020 23:54:26

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:14', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '54d4e31a-e951-4b64-aff8-cacfc993284b' User entered 'No (N)'	System	11 Sep 2020 23:54:26

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:21', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '54d4e31a-e951-4b64-aff8-cacfc993284b' User entered 'None (1)'	System	11 Sep 2020 23:54:26
	System	11 Sep 2020 23:54:26

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:24', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '54d4e31a-e951-4b64-aff8-cacfc993284b' User entered '11 Sep 2020 19:54'	System	11 Sep 2020 23:54:26
	System	11 Sep 2020 23:54:26

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 3'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:07:58', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58f80690-c108-4d9c-98d0-681f5583f1ba'	System	12 Sep 2020 23:08:36
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 23:08:36

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:04', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58f80690-c108-4d9c-98d0-681f5583f1ba'	System	12 Sep 2020 23:08:36
User entered 'No (N)'	System	12 Sep 2020 23:08:36

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:10', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58f80690-c108-4d9c-98d0-681f5583f1ba' User entered 'No (N)'	System	12 Sep 2020 23:08:36

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:15', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58f80690-c108-4d9c-98d0-681f5583f1ba' User entered 'None (1)'	System	12 Sep 2020 23:08:36
	System	12 Sep 2020 23:08:36

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:18', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58f80690-c108-4d9c-98d0-681f5583f1ba'	System	12 Sep 2020 23:08:36
User entered '12 Sep 2020 19:08'	System	12 Sep 2020 23:08:36

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 4'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:32:47', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'e5276a25-05c1-42a0-8b1a-71d850675a9b'	System	14 Sep 2020 00:33:21
User entered 'None (1)'	System	14 Sep 2020 00:33:21

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:32:51', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'e5276a25-05c1-42a0-8b1a-71d850675a9b'	System	14 Sep 2020 00:33:21
User entered 'No (N)'	System	14 Sep 2020 00:33:21

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:33:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'e5276a25-05c1-42a0-8b1a-71d850675a9b'	System	14 Sep 2020 00:33:21
User entered 'No (N)'	System	14 Sep 2020 00:33:21

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:33:14', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'e5276a25-05c1-42a0-8b1a-71d850675a9b'	System	14 Sep 2020 00:33:21
User entered 'None (1)'	System	14 Sep 2020 00:33:21

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:33:18', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'e5276a25-05c1-42a0-8b1a-71d850675a9b'	System	14 Sep 2020 00:33:21
User entered '13 Sep 2020 20:33'	System	14 Sep 2020 00:33:21

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 5'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:23', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a411e5ca-9241-4f82-a0bc-02db89f1113b'	System	14 Sep 2020 23:53:43
User entered 'None (1)'	System	14 Sep 2020 23:53:43

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a411e5ca-9241-4f82-a0bc-02db89f1113b'	System	14 Sep 2020 23:53:43
User entered 'No (N)'	System	14 Sep 2020 23:53:43

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:32', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a411e5ca-9241-4f82-a0bc-02db89f1113b'	System	14 Sep 2020 23:53:43
User entered 'No (N)'	System	14 Sep 2020 23:53:43

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:37', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a411e5ca-9241-4f82-a0bc-02db89f1113b'	System	14 Sep 2020 23:53:43
User entered 'None (1)'	System	14 Sep 2020 23:53:43

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a411e5ca-9241-4f82-a0bc-02db89f1113b'	System	14 Sep 2020 23:53:43
User entered '14 Sep 2020 19:53'	System	14 Sep 2020 23:53:43

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 6'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:33:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c0b51932-8cc2-4186-ad17-2f13567a580f'	System	15 Sep 2020 23:34:11
User entered 'None (1)'	System	15 Sep 2020 23:34:11

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:33:38', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c0b51932-8cc2-4186-ad17-2f13567a580f'	System	15 Sep 2020 23:34:11
User entered 'No (N)'	System	15 Sep 2020 23:34:11

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:33:45', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c0b51932-8cc2-4186-ad17-2f13567a580f'	System	15 Sep 2020 23:34:11
User entered 'No (N)'	System	15 Sep 2020 23:34:11

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:33:53', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c0b51932-8cc2-4186-ad17-2f13567a580f'	System	15 Sep 2020 23:34:11
User entered 'None (1)'	System	15 Sep 2020 23:34:11

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:33:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c0b51932-8cc2-4186-ad17-2f13567a580f'	System	15 Sep 2020 23:34:11
User entered '15 Sep 2020 19:33'	System	15 Sep 2020 23:34:11

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 7'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:04:22', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16c7ae00-196b-4b43-95e8-0f6e0dfc6335'	System	17 Sep 2020 00:04:43
User entered 'None (1)'	System	17 Sep 2020 00:04:43

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:04:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16c7ae00-196b-4b43-95e8-0f6e0dfc6335'	System	17 Sep 2020 00:04:43
User entered 'No (N)'	System	17 Sep 2020 00:04:43

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:04:32', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16c7ae00-196b-4b43-95e8-0f6e0dfc6335'	System	17 Sep 2020 00:04:43
User entered 'No (N)'	System	17 Sep 2020 00:04:43

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:04:38', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16c7ae00-196b-4b43-95e8-0f6e0dfc6335'	System	17 Sep 2020 00:04:43
User entered 'None (1)'	System	17 Sep 2020 00:04:43

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:04:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16c7ae00-196b-4b43-95e8-0f6e0dfc6335'	System	17 Sep 2020 00:04:43
User entered '16 Sep 2020 20:04'	System	17 Sep 2020 00:04:43

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aca86b29-50b1-4ef0-81a9-e7b32416b688'	System	10 Sep 2020 20:54:05
User entered 'None (0)'	System	10 Sep 2020 20:54:05

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:32', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aca86b29-50b1-4ef0-81a9-e7b32416b688'	System	10 Sep 2020 20:54:05
User entered 'None (0)'	System	10 Sep 2020 20:54:05

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:43', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aca86b29-50b1-4ef0-81a9-e7b32416b688'	System	10 Sep 2020 20:54:05
User entered 'None (0)'	System	10 Sep 2020 20:54:05

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:47', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aca86b29-50b1-4ef0-81a9-e7b32416b688'	System	10 Sep 2020 20:54:05
User entered 'No interference with activity (1)'	System	10 Sep 2020 20:54:05

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:51', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aca86b29-50b1-4ef0-81a9-e7b32416b688'	System	10 Sep 2020 20:54:05
User entered 'None (0)'	System	10 Sep 2020 20:54:05

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:54', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aca86b29-50b1-4ef0-81a9-e7b32416b688'	System	10 Sep 2020 20:54:05
User entered 'None (0)'	System	10 Sep 2020 20:54:05

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:58', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aca86b29-50b1-4ef0-81a9-e7b32416b688'	System	10 Sep 2020 20:54:05
User entered 'No (N)'	System	10 Sep 2020 20:54:05

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:54:02', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aca86b29-50b1-4ef0-81a9-e7b32416b688'	System	10 Sep 2020 20:54:05
User entered '10 Sep 2020 16:54'	System	10 Sep 2020 20:54:05

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 16:37'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 19:07'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:30:30', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8aef555a-c49e-4f99-9691-e121a52eb291'	System	11 Sep 2020 01:31:11
User entered 'None (0)'	System	11 Sep 2020 01:31:11

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:30:36', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8aef555a-c49e-4f99-9691-e121a52eb291'	System	11 Sep 2020 01:31:11
User entered 'None (0)'	System	11 Sep 2020 01:31:11

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:30:45', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8aef555a-c49e-4f99-9691-e121a52eb291'	System	11 Sep 2020 01:31:11
User entered 'None (0)'	System	11 Sep 2020 01:31:11

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:30:52', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8aef555a-c49e-4f99-9691-e121a52eb291'	System	11 Sep 2020 01:31:11
User entered 'No interference with activity (1)'	System	11 Sep 2020 01:31:11

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:30:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8aef555a-c49e-4f99-9691-e121a52eb291'	System	11 Sep 2020 01:31:11
User entered 'None (0)'	System	11 Sep 2020 01:31:11

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:31:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8aef555a-c49e-4f99-9691-e121a52eb291'	System	11 Sep 2020 01:31:11
User entered 'None (0)'	System	11 Sep 2020 01:31:11

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:31:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8aef555a-c49e-4f99-9691-e121a52eb291'	System	11 Sep 2020 01:31:11
User entered 'No (N)'	System	11 Sep 2020 01:31:11

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:31:09', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8aef555a-c49e-4f99-9691-e121a52eb291'	System	11 Sep 2020 01:31:11
User entered '10 Sep 2020 21:31'	System	11 Sep 2020 01:31:11

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 20:02'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 2'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:31', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3d638c87-819d-46d1-8fcf-b5c74241fdb1'	System	11 Sep 2020 23:55:08
User entered 'None (0)'	System	11 Sep 2020 23:55:08

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:37', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3d638c87-819d-46d1-8fcf-b5c74241fdb1'	System	11 Sep 2020 23:55:08
User entered 'No interference with activity (1)'	System	11 Sep 2020 23:55:08

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:42', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3d638c87-819d-46d1-8fcf-b5c74241fdb1'	System	11 Sep 2020 23:55:08
User entered 'No interference with activity (1)'	System	11 Sep 2020 23:55:08

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3d638c87-819d-46d1-8fcf-b5c74241fdb1'	System	11 Sep 2020 23:55:08
User entered 'No interference with activity (1)'	System	11 Sep 2020 23:55:08

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:52', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3d638c87-819d-46d1-8fcf-b5c74241fdb1'	System	11 Sep 2020 23:55:08
User entered 'None (0)'	System	11 Sep 2020 23:55:08

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3d638c87-819d-46d1-8fcf-b5c74241fdb1'	System	11 Sep 2020 23:55:08
User entered 'None (0)'	System	11 Sep 2020 23:55:08

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:55:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3d638c87-819d-46d1-8fcf-b5c74241fdb1'	System	11 Sep 2020 23:55:08
User entered 'No (N)'	System	11 Sep 2020 23:55:08

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:55:06', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3d638c87-819d-46d1-8fcf-b5c74241fdb1'	System	11 Sep 2020 23:55:08
User entered '11 Sep 2020 19:55'	System	11 Sep 2020 23:55:08

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 3'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:24', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '7f585484-a695-46a3-84e5-80dc527b2adb'	System	12 Sep 2020 23:08:56
User entered 'None (0)'	System	12 Sep 2020 23:08:56

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:30', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '7f585484-a695-46a3-84e5-80dc527b2adb'	System	12 Sep 2020 23:08:56
User entered 'No interference with activity (1)'	System	12 Sep 2020 23:08:56

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:35', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '7f585484-a695-46a3-84e5-80dc527b2adb'	System	12 Sep 2020 23:08:56
User entered 'No interference with activity (1)'	System	12 Sep 2020 23:08:56

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:39', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '7f585484-a695-46a3-84e5-80dc527b2adb'	System	12 Sep 2020 23:08:56
User entered 'No interference with activity (1)'	System	12 Sep 2020 23:08:56

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:42', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '7f585484-a695-46a3-84e5-80dc527b2adb'	System	12 Sep 2020 23:08:56
User entered 'None (0)'	System	12 Sep 2020 23:08:56

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:45', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '7f585484-a695-46a3-84e5-80dc527b2adb' User entered 'None (0)'	System	12 Sep 2020 23:08:56
	System	12 Sep 2020 23:08:56

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '7f585484-a695-46a3-84e5-80dc527b2adb' User entered 'No (N)'	System	12 Sep 2020 23:08:56

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:53', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '7f585484-a695-46a3-84e5-80dc527b2adb' User entered '12 Sep 2020 19:08'	System	12 Sep 2020 23:08:56
	System	12 Sep 2020 23:08:56

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 4'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:33:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6f8246df-d215-4d83-bcd5-b87583dbee82'	System	14 Sep 2020 00:34:08
User entered 'None (0)'	System	14 Sep 2020 00:34:08

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:33:32', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6f8246df-d215-4d83-bcd5-b87583dbee82'	System	14 Sep 2020 00:34:08
User entered 'No interference with activity (1)'	System	14 Sep 2020 00:34:08

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:33:42', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6f8246df-d215-4d83-bcd5-b87583dbee82'	System	14 Sep 2020 00:34:08
User entered 'No interference with activity (1)'	System	14 Sep 2020 00:34:08

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:33:49', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6f8246df-d215-4d83-bcd5-b87583dbee82'	System	14 Sep 2020 00:34:08
User entered 'No interference with activity (1)'	System	14 Sep 2020 00:34:08

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:33:53', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6f8246df-d215-4d83-bcd5-b87583dbee82'	System	14 Sep 2020 00:34:08
User entered 'None (0)'	System	14 Sep 2020 00:34:08

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:33:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6f8246df-d215-4d83-bcd5-b87583dbee82'	System	14 Sep 2020 00:34:08
User entered 'None (0)'	System	14 Sep 2020 00:34:08

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:34:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6f8246df-d215-4d83-bcd5-b87583dbee82'	System	14 Sep 2020 00:34:08
User entered 'No (N)'	System	14 Sep 2020 00:34:08

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:34:06', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6f8246df-d215-4d83-bcd5-b87583dbee82'	System	14 Sep 2020 00:34:08
User entered '13 Sep 2020 20:34'	System	14 Sep 2020 00:34:08

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 5'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d19a100-1505-4659-8e7d-085b6b19b543'	System	14 Sep 2020 23:54:32
User entered 'None (0)'	System	14 Sep 2020 23:54:32

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d19a100-1505-4659-8e7d-085b6b19b543'	System	14 Sep 2020 23:54:32
User entered 'No interference with activity (1)'	System	14 Sep 2020 23:54:32

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:54:09', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d19a100-1505-4659-8e7d-085b6b19b543'	System	14 Sep 2020 23:54:32
User entered 'Some interference with activity (2)'	System	14 Sep 2020 23:54:32

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:54:13', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d19a100-1505-4659-8e7d-085b6b19b543'	System	14 Sep 2020 23:54:32
User entered 'Some interference with activity (2)'	System	14 Sep 2020 23:54:32

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:54:17', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d19a100-1505-4659-8e7d-085b6b19b543'	System	14 Sep 2020 23:54:32
User entered 'None (0)'	System	14 Sep 2020 23:54:32

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:54:20', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d19a100-1505-4659-8e7d-085b6b19b543'	System	14 Sep 2020 23:54:32
User entered 'None (0)'	System	14 Sep 2020 23:54:32

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:54:24', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d19a100-1505-4659-8e7d-085b6b19b543'	System	14 Sep 2020 23:54:32
User entered 'No (N)'	System	14 Sep 2020 23:54:32

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:54:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d19a100-1505-4659-8e7d-085b6b19b543'	System	14 Sep 2020 23:54:32
User entered '14 Sep 2020 19:54'	System	14 Sep 2020 23:54:32

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 6'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:34:25', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd1ac9706-423b-49c8-828c-8dd5c162d62e'	System	15 Sep 2020 23:35:09
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	15 Sep 2020 23:35:09

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:34:32', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd1ac9706-423b-49c8-828c-8dd5c162d62e'	System	15 Sep 2020 23:35:09
User entered 'No interference with activity (1)'	System	15 Sep 2020 23:35:09

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:34:44', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd1ac9706-423b-49c8-828c-8dd5c162d62e'	System	15 Sep 2020 23:35:09
User entered 'No interference with activity (1)'	System	15 Sep 2020 23:35:09

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:34:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd1ac9706-423b-49c8-828c-8dd5c162d62e'	System	15 Sep 2020 23:35:09
User entered 'No interference with activity (1)'	System	15 Sep 2020 23:35:09

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:34:54', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd1ac9706-423b-49c8-828c-8dd5c162d62e'	System	15 Sep 2020 23:35:09
User entered 'None (0)'	System	15 Sep 2020 23:35:09

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:34:57', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd1ac9706-423b-49c8-828c-8dd5c162d62e'	System	15 Sep 2020 23:35:09
User entered 'None (0)'	System	15 Sep 2020 23:35:09

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:35:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd1ac9706-423b-49c8-828c-8dd5c162d62e'	System	15 Sep 2020 23:35:09
User entered 'No (N)'	System	15 Sep 2020 23:35:09

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:35:07', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd1ac9706-423b-49c8-828c-8dd5c162d62e'	System	15 Sep 2020 23:35:09
User entered '15 Sep 2020 19:35'	System	15 Sep 2020 23:35:09

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 20:20:29
User entered 'Day 7'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:04:49', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '63797e67-76ee-4054-9189-ec8d26e0423b'	System	17 Sep 2020 00:05:31
User entered 'None (0)'	System	17 Sep 2020 00:05:31

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:05:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '63797e67-76ee-4054-9189-ec8d26e0423b'	System	17 Sep 2020 00:05:31
User entered 'None (0)'	System	17 Sep 2020 00:05:31

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:05:04', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '63797e67-76ee-4054-9189-ec8d26e0423b'	System	17 Sep 2020 00:05:31
User entered 'No interference with activity (1)'	System	17 Sep 2020 00:05:31

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:05:08', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '63797e67-76ee-4054-9189-ec8d26e0423b'	System	17 Sep 2020 00:05:31
User entered 'No interference with activity (1)'	System	17 Sep 2020 00:05:31

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:05:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '63797e67-76ee-4054-9189-ec8d26e0423b'	System	17 Sep 2020 00:05:31
User entered 'None (0)'	System	17 Sep 2020 00:05:31

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:05:15', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '63797e67-76ee-4054-9189-ec8d26e0423b'	System	17 Sep 2020 00:05:31
User entered 'None (0)'	System	17 Sep 2020 00:05:31

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:05:25', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '63797e67-76ee-4054-9189-ec8d26e0423b'	System	17 Sep 2020 00:05:31
User entered 'No (N)'	System	17 Sep 2020 00:05:31

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:05:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '63797e67-76ee-4054-9189-ec8d26e0423b'	System	17 Sep 2020 00:05:31
User entered '16 Sep 2020 20:05'	System	17 Sep 2020 00:05:31

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:20:29

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 23:35:09
User entered 'Day 8'	System	15 Sep 2020 23:35:09

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-17T19:44:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b2b1c142-b15b-4897-a755-8b95101653e0'	System	17 Sep 2020 23:44:37
User entered 'Some interference with activity (2)'	System	17 Sep 2020 23:44:37

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-17T19:44:35', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b2b1c142-b15b-4897-a755-8b95101653e0'	System	17 Sep 2020 23:44:37
User entered '17 Sep 2020 19:44'	System	17 Sep 2020 23:44:37

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 23:35:09

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 23:35:09

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 00:05:31
User entered 'Day 9'	System	17 Sep 2020 00:05:31

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-18T20:53:23', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b5efe13a-96eb-4570-8b2b-beb1404830a4'	System	19 Sep 2020 00:53:29
User entered 'Some interference with activity (2)'	System	19 Sep 2020 00:53:29

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-18T20:53:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b5efe13a-96eb-4570-8b2b-beb1404830a4'	System	19 Sep 2020 00:53:29
User entered '18 Sep 2020 20:53'	System	19 Sep 2020 00:53:29

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 00:05:31

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 00:05:31

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 23:44:37
User entered 'Day 10'	System	17 Sep 2020 23:44:37

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-19T19:25:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3c2adf27-af40-4f54-9b9f-365a857861aa'	System	19 Sep 2020 23:25:44
User entered 'No interference with activity (1)'	System	19 Sep 2020 23:25:44

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-19T19:25:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3c2adf27-af40-4f54-9b9f-365a857861aa'	System	19 Sep 2020 23:25:44
User entered '19 Sep 2020 19:25'	System	19 Sep 2020 23:25:44

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 23:44:37

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 23:44:37

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Sep 2020 00:53:29
User entered 'Day 11'	System	19 Sep 2020 00:53:29

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T05:08:21', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '67da9aaf-210b-41f6-a48c-40adceac95fd'	System	21 Sep 2020 09:08:27
User entered 'No interference with activity (1)'	System	21 Sep 2020 09:08:27

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T05:08:25', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '67da9aaf-210b-41f6-a48c-40adceac95fd' User entered '21 Sep 2020 05:08'	System	21 Sep 2020 09:08:27
	System	21 Sep 2020 09:08:27

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 00:53:29

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 00:53:29

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Sep 2020 23:25:44
User entered 'Day 12'	System	19 Sep 2020 23:25:44

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T15:28:57', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a3e2b811-7997-479f-b31b-6c5dec70b683'	System	21 Sep 2020 19:29:03
User entered 'No interference with activity (1)'	System	21 Sep 2020 19:29:03

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T15:29:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a3e2b811-7997-479f-b31b-6c5dec70b683'	System	21 Sep 2020 19:29:03
User entered '21 Sep 2020 15:29'	System	21 Sep 2020 19:29:03

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 23:25:44

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 23:25:44

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 09:08:27
User entered 'Day 13'	System	21 Sep 2020 09:08:27

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 09:08:27

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 09:08:27

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 19:29:03
User entered 'Day 14'	System	21 Sep 2020 19:29:03

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-24T08:18:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3bfde9ff-e687-476d-b56d-3562277b8cc1'	System	24 Sep 2020 12:18:54
User entered 'No interference with activity (1)'	System	24 Sep 2020 12:18:54

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-24T08:18:51', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3bfde9ff-e687-476d-b56d-3562277b8cc1'	System	24 Sep 2020 12:18:54
User entered '24 Sep 2020 08:18'	System	24 Sep 2020 12:18:54

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 19:29:03

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 19:29:03

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 12:18:54
User entered 'Day 15'	System	24 Sep 2020 12:18:54

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-25T11:40:09', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f556dbe2-bb47-4aeb-b9e5-94ee59ffa8b7'	System	25 Sep 2020 15:40:17
User entered 'No interference with activity (1)'	System	25 Sep 2020 15:40:17

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-25T11:40:15', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f556dbe2-bb47-4aeb-b9e5-94ee59ffa8b7'	System	25 Sep 2020 15:40:17
User entered '25 Sep 2020 11:40'	System	25 Sep 2020 15:40:17

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	24 Sep 2020 12:18:54

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 12:18:54

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 12:18:54
User entered 'Day 16'	System	24 Sep 2020 12:18:54

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T00:00:47', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9762326c-645a-4667-889d-77b705fd36b1'	System	26 Sep 2020 04:00:55
User entered 'No interference with activity (1)'	System	26 Sep 2020 04:00:55

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T00:00:49', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9762326c-645a-4667-889d-77b705fd36b1'	System	26 Sep 2020 04:00:55
User entered '26 Sep 2020 00:00'	System	26 Sep 2020 04:00:55

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 12:18:54

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 12:18:54

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 15:40:17
User entered 'Day 17'	System	25 Sep 2020 15:40:17

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T17:11:57', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '21853852-1776-4a79-941e-fe2abf6fceb1'	System	26 Sep 2020 21:12:04
User entered 'No interference with activity (1)'	System	26 Sep 2020 21:12:04

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T17:12:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '21853852-1776-4a79-941e-fe2abf6fceb1'	System	26 Sep 2020 21:12:04
User entered '26 Sep 2020 17:12'	System	26 Sep 2020 21:12:04

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 15:40:17

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 15:40:17

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 04:00:55
User entered 'Day 18'	System	26 Sep 2020 04:00:55

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-27T19:12:26', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '4009a743-c699-447b-99f5-17c2f370ad2c'	System	27 Sep 2020 23:12:34
User entered 'No interference with activity (1)'	System	27 Sep 2020 23:12:34

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-27T19:12:30', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '4009a743-c699-447b-99f5-17c2f370ad2c'	System	27 Sep 2020 23:12:34
User entered '27 Sep 2020 19:12'	System	27 Sep 2020 23:12:34

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 04:00:55

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 04:00:55

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 21:12:04
User entered 'Day 19'	System	26 Sep 2020 21:12:04

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 21:12:04

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 21:12:04

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Sep 2020 23:12:34
User entered 'Day 20'	System	27 Sep 2020 23:12:34

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-29T15:32:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1c8b7ed9-7c95-4c89-9ec8-7a5d8d6e74c8'	System	29 Sep 2020 19:32:12
User entered 'No interference with activity (1)'	System	29 Sep 2020 19:32:12

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-29T15:32:09', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1c8b7ed9-7c95-4c89-9ec8-7a5d8d6e74c8'	System	29 Sep 2020 19:32:12
User entered '29 Sep 2020 15:32'	System	29 Sep 2020 19:32:12

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 23:12:34

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 23:12:34

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 19:32:12
User entered 'Day 21'	System	29 Sep 2020 19:32:12

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 19:32:12

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 19:32:12

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 19:32:12
User entered 'Day 22'	System	29 Sep 2020 19:32:12

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-01T20:31:08', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0e3536db-f150-4885-8b34-09b1a55e9391'	System	02 Oct 2020 00:31:14
User entered 'No interference with activity (1)'	System	02 Oct 2020 00:31:14

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-01T20:31:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0e3536db-f150-4885-8b34-09b1a55e9391'	System	02 Oct 2020 00:31:14
User entered '01 Oct 2020 20:31'	System	02 Oct 2020 00:31:14

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 19:32:12

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 19:32:12

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 00:31:14
User entered 'Day 23'	System	02 Oct 2020 00:31:14

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-02T20:26:25', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6be4e1ef-ee1b-4163-8002-39a1efc9e793'	System	03 Oct 2020 00:26:33
User entered 'No interference with activity (1)'	System	03 Oct 2020 00:26:33

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-02T20:26:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6be4e1ef-ee1b-4163-8002-39a1efc9e793'	System	03 Oct 2020 00:26:33
User entered '02 Oct 2020 20:26'	System	03 Oct 2020 00:26:33

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	02 Oct 2020 00:31:14

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 00:31:14

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 00:31:14
User entered 'Day 24'	System	02 Oct 2020 00:31:14

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-03T20:47:44', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '35a97f77-06c5-4ab5-b4e8-0bef4ddc7ba8'	System	04 Oct 2020 00:47:53
User entered 'None (0)'	System	04 Oct 2020 00:47:53

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-03T20:47:48', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '35a97f77-06c5-4ab5-b4e8-0bef4ddc7ba8'	System	04 Oct 2020 00:47:53
User entered '03 Oct 2020 20:47'	System	04 Oct 2020 00:47:53

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 00:31:14

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 00:31:14

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 23:35:09
User entered 'Day 8'	System	15 Sep 2020 23:35:09

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-17T19:44:48', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '4a79b87e-0f91-4b94-a50f-f2a84e6a9f65'	System	17 Sep 2020 23:44:54
User entered 'No interference with activity (1)'	System	17 Sep 2020 23:44:54

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-17T19:44:52', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '4a79b87e-0f91-4b94-a50f-f2a84e6a9f65'	System	17 Sep 2020 23:44:54
User entered '17 Sep 2020 19:44'	System	17 Sep 2020 23:44:54

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 23:35:09

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 23:35:09

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 00:05:31
User entered 'Day 9'	System	17 Sep 2020 00:05:31

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-18T20:53:36', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c2341a1c-e3ac-49d8-ab6f-d4de0c677866'	System	19 Sep 2020 00:53:45
User entered 'Some interference with activity (2)'	System	19 Sep 2020 00:53:45

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-18T20:53:40', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c2341a1c-e3ac-49d8-ab6f-d4de0c677866'	System	19 Sep 2020 00:53:45
User entered '18 Sep 2020 20:53'	System	19 Sep 2020 00:53:45

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 00:05:31

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 00:05:31

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 23:44:54
User entered 'Day 10'	System	17 Sep 2020 23:44:54

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-19T19:25:19', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '48a562c6-5da0-4941-b124-54b888e143ac'	System	19 Sep 2020 23:25:30
User entered 'No interference with activity (1)'	System	19 Sep 2020 23:25:30

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-19T19:25:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '48a562c6-5da0-4941-b124-54b888e143ac'	System	19 Sep 2020 23:25:30
User entered '19 Sep 2020 19:25'	System	19 Sep 2020 23:25:30

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 23:44:54

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 23:44:54

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Sep 2020 00:53:45
User entered 'Day 11'	System	19 Sep 2020 00:53:45

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T05:08:09', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5d323681-e29d-4918-beb0-8f86d04414d3'	System	21 Sep 2020 09:08:26
User entered 'No interference with activity (1)'	System	21 Sep 2020 09:08:26

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T05:08:13', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5d323681-e29d-4918-beb0-8f86d04414d3'	System	21 Sep 2020 09:08:26
User entered '21 Sep 2020 05:08'	System	21 Sep 2020 09:08:26

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 00:53:45

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 00:53:45

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Sep 2020 23:25:30
User entered 'Day 12'	System	19 Sep 2020 23:25:30

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T15:28:44', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '30c8c0ce-5d5d-4105-8154-3defd2fb5734'	System	21 Sep 2020 19:28:50
User entered 'No interference with activity (1)'	System	21 Sep 2020 19:28:50

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T15:28:48', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '30c8c0ce-5d5d-4105-8154-3defd2fb5734'	System	21 Sep 2020 19:28:50
User entered '21 Sep 2020 15:28'	System	21 Sep 2020 19:28:50

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 23:25:30

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 23:25:30

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 09:08:26
User entered 'Day 13'	System	21 Sep 2020 09:08:26

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 09:08:26

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 09:08:26

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 19:28:50
User entered 'Day 14'	System	21 Sep 2020 19:28:50

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-24T08:19:23', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a7933152-2928-495b-97ee-57a40d974d97'	System	24 Sep 2020 12:19:31
User entered 'No interference with activity (1)'	System	24 Sep 2020 12:19:31

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-24T08:19:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a7933152-2928-495b-97ee-57a40d974d97'	System	24 Sep 2020 12:19:31
User entered '24 Sep 2020 08:19'	System	24 Sep 2020 12:19:31

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 19:28:50

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 19:28:50

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 12:19:31
User entered 'Day 15'	System	24 Sep 2020 12:19:31

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-25T11:39:58', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '4d7b890a-bbba-4624-bed6-77a53466e388'	System	25 Sep 2020 15:40:05
User entered 'No interference with activity (1)'	System	25 Sep 2020 15:40:05

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-25T11:40:02', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '4d7b890a-bbba-4624-bed6-77a53466e388'	System	25 Sep 2020 15:40:05
User entered '25 Sep 2020 11:40'	System	25 Sep 2020 15:40:05

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	24 Sep 2020 12:19:31

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 12:19:31

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 12:19:31
User entered 'Day 16'	System	24 Sep 2020 12:19:31

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T00:00:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '46326e79-43a4-4b6b-af0d-423ca71537f8'	System	26 Sep 2020 04:00:45
User entered 'No interference with activity (1)'	System	26 Sep 2020 04:00:45

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T00:00:36', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '46326e79-43a4-4b6b-af0d-423ca71537f8'	System	26 Sep 2020 04:00:45
User entered '26 Sep 2020 00:00'	System	26 Sep 2020 04:00:45

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 12:19:31

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 12:19:31

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 15:40:05
User entered 'Day 17'	System	25 Sep 2020 15:40:05

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T17:11:43', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '634a2701-6134-43bb-82b2-809e11f0139d'	System	26 Sep 2020 21:11:49
User entered 'No interference with activity (1)'	System	26 Sep 2020 21:11:49

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T17:11:47', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '634a2701-6134-43bb-82b2-809e11f0139d'	System	26 Sep 2020 21:11:49
User entered '26 Sep 2020 17:11'	System	26 Sep 2020 21:11:49

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 15:40:05

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 15:40:05

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 04:00:45
User entered 'Day 18'	System	26 Sep 2020 04:00:45

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-27T19:12:14', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '2a6282ab-874f-4bc7-a95a-c80dd38d2c1b'	System	27 Sep 2020 23:12:19
User entered 'No interference with activity (1)'	System	27 Sep 2020 23:12:19

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-27T19:12:18', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '2a6282ab-874f-4bc7-a95a-c80dd38d2c1b'	System	27 Sep 2020 23:12:19
User entered '27 Sep 2020 19:12'	System	27 Sep 2020 23:12:19

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 04:00:45

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 04:00:45

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 21:11:49
User entered 'Day 19'	System	26 Sep 2020 21:11:49

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 21:11:49

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 21:11:49

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Sep 2020 23:12:19
User entered 'Day 20'	System	27 Sep 2020 23:12:19

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 26 Nov 2020 09:25:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-29T15:31:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1bb09e55-a8b3-41cf-9937-ce4c5152dce1'	System	29 Sep 2020 19:32:04
User entered 'None (0)'	System	29 Sep 2020 19:32:04

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-29T15:32:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1bb09e55-a8b3-41cf-9937-ce4c5152dce1'	System	29 Sep 2020 19:32:04
User entered '29 Sep 2020 15:32'	System	29 Sep 2020 19:32:04

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 23:12:19

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 23:12:19

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 23:33:26
User entered 'Day 8'	System	15 Sep 2020 23:33:26

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-17T19:45:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e932b6d-fe6a-4207-a45c-3e00653f26b6'	System	17 Sep 2020 23:45:05
User entered 'No (N)'	System	17 Sep 2020 23:45:05

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-17T19:45:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e932b6d-fe6a-4207-a45c-3e00653f26b6'	System	17 Sep 2020 23:45:05
User entered '17 Sep 2020 19:45'	System	17 Sep 2020 23:45:05

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 23:33:26

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 23:33:26

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 00:05:31
User entered 'Day 9'	System	17 Sep 2020 00:05:31

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-18T20:53:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c6c71e2c-8ef8-47ee-9971-970c48577471'	System	19 Sep 2020 00:53:07
User entered 'No (N)'	System	19 Sep 2020 00:53:07

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-18T20:53:04', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c6c71e2c-8ef8-47ee-9971-970c48577471'	System	19 Sep 2020 00:53:07
User entered '18 Sep 2020 20:53'	System	19 Sep 2020 00:53:07

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 00:05:31

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 00:05:31

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 23:44:37
User entered 'Day 10'	System	17 Sep 2020 23:44:37

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-19T19:25:08', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8f617029-2be4-47a4-a12b-db18c1e97da4'	System	19 Sep 2020 23:25:13
User entered 'No (N)'	System	19 Sep 2020 23:25:13

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-19T19:25:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8f617029-2be4-47a4-a12b-db18c1e97da4'	System	19 Sep 2020 23:25:13
User entered '19 Sep 2020 19:25'	System	19 Sep 2020 23:25:13

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 23:44:37

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 23:44:37

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Sep 2020 00:53:29
User entered 'Day 11'	System	19 Sep 2020 00:53:29

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T05:07:43', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '46306563-5bcd-463c-a4ec-4db4cf4631e8'	System	21 Sep 2020 09:08:00
User entered 'No (N)'	System	21 Sep 2020 09:08:00

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T05:07:58', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '46306563-5bcd-463c-a4ec-4db4cf4631e8'	System	21 Sep 2020 09:08:00
User entered '21 Sep 2020 05:07'	System	21 Sep 2020 09:08:00

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 00:53:29

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 00:53:29

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Sep 2020 23:25:30
User entered 'Day 12'	System	19 Sep 2020 23:25:30

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T15:28:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '24ea314f-b3c6-44aa-a6ae-4c996ab9363f'	System	21 Sep 2020 19:28:41
User entered 'No (N)'	System	21 Sep 2020 19:28:41

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T15:28:37', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '24ea314f-b3c6-44aa-a6ae-4c996ab9363f' User entered '21 Sep 2020 15:28'	System	21 Sep 2020 19:28:41
	System	21 Sep 2020 19:28:41

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	19 Sep 2020 23:25:30

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	19 Sep 2020 23:25:30

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 09:08:26
User entered 'Day 13'	System	21 Sep 2020 09:08:26

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 09:08:26

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 09:08:26

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 19:28:50
User entered 'Day 14'	System	21 Sep 2020 19:28:50

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-24T08:19:06', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '288f36ae-2536-4b00-8abc-51e866cc31e9'	System	24 Sep 2020 12:19:12
User entered 'Yes (Y)'	System	24 Sep 2020 12:19:12

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-24T08:19:11', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '288f36ae-2536-4b00-8abc-51e866cc31e9'	System	24 Sep 2020 12:19:12
User entered '24 Sep 2020 08:19'	System	24 Sep 2020 12:19:12

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 19:28:50

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 19:28:50

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 12:18:54
User entered 'Day 15'	System	24 Sep 2020 12:18:54

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-25T11:39:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b7a20f36-06c9-43d9-b34a-365635ad1583'	System	25 Sep 2020 15:39:55
User entered 'No (N)'	System	25 Sep 2020 15:39:55

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-25T11:39:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b7a20f36-06c9-43d9-b34a-365635ad1583'	System	25 Sep 2020 15:39:55
User entered '25 Sep 2020 11:39'	System	25 Sep 2020 15:39:55

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	24 Sep 2020 12:18:54

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 12:18:54

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 12:18:54
User entered 'Day 16'	System	24 Sep 2020 12:18:54

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T00:00:25', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd34b448d-113e-4832-90cc-4ecc4f14d83d'	System	26 Sep 2020 04:00:32
User entered 'No (N)'	System	26 Sep 2020 04:00:32

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T00:00:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd34b448d-113e-4832-90cc-4ecc4f14d83d'	System	26 Sep 2020 04:00:32
User entered '26 Sep 2020 00:00'	System	26 Sep 2020 04:00:32

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 12:18:54

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 12:18:54

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	25 Sep 2020 15:40:05
User entered 'Day 17'	System	25 Sep 2020 15:40:05

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T17:11:29', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f65c066d-2eed-405a-b930-95c4b7f6d199'	System	26 Sep 2020 21:11:36
User entered 'No (N)'	System	26 Sep 2020 21:11:36

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T17:11:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f65c066d-2eed-405a-b930-95c4b7f6d199'	System	26 Sep 2020 21:11:36
User entered '26 Sep 2020 17:11'	System	26 Sep 2020 21:11:36

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 15:40:05

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 15:40:05

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 04:00:45
User entered 'Day 18'	System	26 Sep 2020 04:00:45

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-27T19:11:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '01910572-c373-45e5-a512-842e04d20cd9'	System	27 Sep 2020 23:12:05
User entered 'No (N)'	System	27 Sep 2020 23:12:05

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-27T19:12:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '01910572-c373-45e5-a512-842e04d20cd9'	System	27 Sep 2020 23:12:05
User entered '27 Sep 2020 19:12'	System	27 Sep 2020 23:12:05

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 04:00:45

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 04:00:45

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Sep 2020 21:11:49
User entered 'Day 19'	System	26 Sep 2020 21:11:49

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 21:11:49

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 21:11:49

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Sep 2020 23:12:19
User entered 'Day 20'	System	27 Sep 2020 23:12:19

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-29T15:31:45', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b0f604c3-6efe-4a27-a8d0-ab4328de11e7'	System	29 Sep 2020 19:32:00
User entered 'No (N)'	System	29 Sep 2020 19:32:00

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-29T15:31:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b0f604c3-6efe-4a27-a8d0-ab4328de11e7'	System	29 Sep 2020 19:32:00
User entered '29 Sep 2020 15:31'	System	29 Sep 2020 19:32:00

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 23:12:19

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 23:12:19

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 19:32:12
User entered 'Day 21'	System	29 Sep 2020 19:32:12

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 19:32:12

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 19:32:12

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 19:32:12
User entered 'Day 22'	System	29 Sep 2020 19:32:12

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-01T20:30:58', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a2f09d68-dd92-4de1-bc2c-3e731af791a2'	System	02 Oct 2020 00:31:05
User entered 'No (N)'	System	02 Oct 2020 00:31:05

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-01T20:31:02', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a2f09d68-dd92-4de1-bc2c-3e731af791a2'	System	02 Oct 2020 00:31:05
User entered '01 Oct 2020 20:31'	System	02 Oct 2020 00:31:05

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 19:32:12

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 19:32:12

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 00:31:14
User entered 'Day 23'	System	02 Oct 2020 00:31:14

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-02T20:26:14', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '55d9fad9-673e-4f38-aad7-66dbd2f81a18'	System	03 Oct 2020 00:26:19
User entered 'No (N)'	System	03 Oct 2020 00:26:19

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-02T20:26:17', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '55d9fad9-673e-4f38-aad7-66dbd2f81a18'	System	03 Oct 2020 00:26:19
User entered '02 Oct 2020 20:26'	System	03 Oct 2020 00:26:19

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	02 Oct 2020 00:31:14

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 00:31:14

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Oct 2020 00:31:14
User entered 'Day 24'	System	02 Oct 2020 00:31:14

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-03T20:47:35', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b41504e4-ef29-4eaf-9e64-6f1a8a52937a'	System	04 Oct 2020 00:47:41
User entered 'No (N)'	System	04 Oct 2020 00:47:41

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 09:25:59

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-03T20:47:38', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b41504e4-ef29-4eaf-9e64-6f1a8a52937a' User entered '03 Oct 2020 20:47'	System	04 Oct 2020 00:47:41
	System	04 Oct 2020 00:47:41

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 09:25:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 00:31:14

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 26 Nov 2020 09:25:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 00:31:14

US3402284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Sep 2020 18:55:58

US3402284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Traci Hull (b) (4) (b) (4)	17 Sep 2020 18:55:58

US3402284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[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)	17 Sep 2020 18:55:58

US3402284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	17 Sep 2020 18:55:58

US3402284

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	17 Sep 2020 18:56:02

US3402284

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 18:56:02

US3402284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Oct 2020 15:17:43

US3402284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Traci Hull (b) (4) (b) (4)	08 Oct 2020 15:17:43

US3402284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[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)	08 Oct 2020 15:17:43

US3402284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Oct 2020 15:17:43

US3402284

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 20:12:04

US3402284

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 20:12:04

US3402284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 20:12:25

US3402284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:47:45
User entered '2 Oct 2020'	Traci Hull (b) (4)	05 Oct 2020 20:12:25

US3402284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[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)	05 Oct 2020 20:12:25

US3402284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Oct 2020 20:12:25

US3402284

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 20:12:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Oct 2020 20:12:35
User entered 'Yes (Y)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	05 Oct 2020 20:12:35
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 20:12:29
User entered empty.	Traci Hull (b) (4) (b) (4)	05 Oct 2020 20:12:29

US3402284

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 20:12:35
User entered empty.	System	05 Oct 2020 20:12:29

US3402284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Oct 2020 20:39:46

US3402284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '08 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:48:50
User entered '8 Oct 2020'	Traci Hull (b) (4)	08 Oct 2020 20:39:46

US3402284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:59

[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)	08 Oct 2020 20:39:46

US3402284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:59

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	08 Oct 2020 20:39:46

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Oct 2020 20:41:43

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:49:02
User entered '8 Oct 2020'	Traci Hull (b) (4)	08 Oct 2020 20:41:43

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '15:04'	Traci Hull (b) (4) (b) (4)	08 Oct 2020 20:41:43

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '08 Oct 2020 15:04'	System	11 Nov 2020 12:49:02
User entered '8 Oct 2020 15:04'	System	08 Oct 2020 20:41:43

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	Traci Hull (b) (4) (b) (4)	08 Oct 2020 20:41:43

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	08 Oct 2020 20:41:43

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Oct 2020 20:41:43

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '88'	Traci Hull (b) (4) (b) (4)	08 Oct 2020 20:41:43

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Oct 2020 20:41:43

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '14'	Traci Hull (b) (4) (b) (4)	08 Oct 2020 20:41:43

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Oct 2020 20:41:43

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '122'	Traci Hull (b) (4) (b) (4)	08 Oct 2020 20:41:43

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 20:41:43

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80'	Traci Hull (b) (4) (b) (4)	08 Oct 2020 20:41:43

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 20:41:43

US3402284

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	08 Oct 2020 20:41:51

US3402284

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	08 Oct 2020 20:41:51

US3402284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Oct 2020 20:42:02

US3402284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:49:18
User entered '8 Oct 2020'	Traci Hull (b) (4)	08 Oct 2020 20:42:02

US3402284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '15:17'	Traci Hull (b) (4) (b) (4)	08 Oct 2020 20:42:02

US3402284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered '08 Oct 2020 15:17'	System	11 Nov 2020 12:49:18
User entered '8 Oct 2020 15:17'	System	08 Oct 2020 20:42:02

US3402284

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	08 Oct 2020 20:42:06

US3402284

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 20:42:06

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 64'	System	08 Aug 2020 13:01:15

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:52:20
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'Patient was contacted patient was feeling sick due to kidney stones. AE has already been added. no further action is needed' (Site from DM).	Tammy Kohn (b) (4)	02 Nov 2020 14:43:36
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 07:03:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-08T14:27:36', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '57e4cab2-5eea-4628-828f-3d8f907f6ccb'	System	08 Oct 2020 18:28:45
User entered 'Yes (Y)'	System	08 Oct 2020 18:28:45

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-08T14:27:44', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '57e4cab2-5eea-4628-828f-3d8f907f6ccb' User entered 'Yes (Y)'	System	08 Oct 2020 18:28:45
	System	08 Oct 2020 18:28:45

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-08T14:28:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '57e4cab2-5eea-4628-828f-3d8f907f6ccb'	System	08 Oct 2020 18:28:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Oct 2020 18:28:45

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-08T14:28:09', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '57e4cab2-5eea-4628-828f-3d8f907f6ccb' User entered 'No (N)'	System	08 Oct 2020 18:28:45

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-08T14:28:17', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '57e4cab2-5eea-4628-828f-3d8f907f6ccb' User entered 'Yes (Y)'	System	08 Oct 2020 18:28:45
	System	08 Oct 2020 18:28:45

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-08T14:28:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '57e4cab2-5eea-4628-828f-3d8f907f6ccb'	System	08 Oct 2020 18:28:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Oct 2020 18:28:45

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-08T14:28:34', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '57e4cab2-5eea-4628-828f-3d8f907f6ccb' User entered '08 Oct 2020 14:28:34'	System	08 Oct 2020 18:28:45
	System	08 Oct 2020 18:28:45

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered '08 Oct 2020 00:01'	System	08 Aug 2020 13:01:15

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered '12 Oct 2020 23:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 71'	System	08 Aug 2020 13:01:15

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-15T10:29:09', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd90afd8e-1bd6-4380-bb20-b63e8faad12e'	System	15 Oct 2020 14:30:23
User entered 'No (N)'	System	15 Oct 2020 14:30:23

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-15T10:29:19', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd90afd8e-1bd6-4380-bb20-b63e8faad12e'	System	15 Oct 2020 14:30:23
User entered 'Yes (Y)'	System	15 Oct 2020 14:30:23

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-15T10:29:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd90afd8e-1bd6-4380-bb20-b63e8faad12e'	System	15 Oct 2020 14:30:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Oct 2020 14:30:23

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-15T10:29:38', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd90afd8e-1bd6-4380-bb20-b63e8faad12e'	System	15 Oct 2020 14:30:23
User entered '15 Oct 2020 10:29:38'	System	15 Oct 2020 14:30:23

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered '15 Oct 2020 00:01'	System	08 Aug 2020 13:01:15

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered '19 Oct 2020 23:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 78'	System	08 Aug 2020 13:01:15

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-22T20:20:52', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5ac93e84-ba57-4546-b6c5-5244ed557959'	System	23 Oct 2020 00:21:57
User entered 'No (N)'	System	23 Oct 2020 00:21:57

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-22T20:21:44', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5ac93e84-ba57-4546-b6c5-5244ed557959'	System	23 Oct 2020 00:21:57
User entered 'No (N)'	System	23 Oct 2020 00:21:57

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-22T20:21:55', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5ac93e84-ba57-4546-b6c5-5244ed557959' User entered '22 Oct 2020 20:21:55'	System	23 Oct 2020 00:21:57
	System	23 Oct 2020 00:21:57

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered '22 Oct 2020 00:01'	System	08 Aug 2020 13:01:15

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered '26 Oct 2020 23:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 92'	System	08 Aug 2020 13:01:15

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-05T15:45:11', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1e08403c-74cd-4c43-a554-553b61476a73'	System	05 Nov 2020 20:45:42
User entered 'No (N)'	System	05 Nov 2020 20:45:42

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-05T15:45:22', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1e08403c-74cd-4c43-a554-553b61476a73'	System	05 Nov 2020 20:45:42
User entered 'No (N)'	System	05 Nov 2020 20:45:42

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-05T15:45:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1e08403c-74cd-4c43-a554-553b61476a73' User entered '05 Nov 2020 15:45:33'	System	05 Nov 2020 20:45:42
	System	05 Nov 2020 20:45:42

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered '05 Nov 2020 00:01'	System	08 Aug 2020 13:01:15

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered '09 Nov 2020 23:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered 'Day 99'	System	08 Aug 2020 13:01:15

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-12T10:33:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bfde2e34-09a9-4c04-b41b-33af73d5e1e3'	System	12 Nov 2020 15:33:33
User entered 'No (N)'	System	12 Nov 2020 15:33:33

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-12T10:33:24', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bfde2e34-09a9-4c04-b41b-33af73d5e1e3'	System	12 Nov 2020 15:33:33
User entered 'No (N)'	System	12 Nov 2020 15:33:33

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-12T10:33:30', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bfde2e34-09a9-4c04-b41b-33af73d5e1e3'	System	12 Nov 2020 15:33:33
User entered '12 Nov 2020 10:33:30'	System	12 Nov 2020 15:33:33

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered '12 Nov 2020 00:01'	System	08 Aug 2020 13:01:15

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	08 Aug 2020 13:01:15
User entered '16 Nov 2020 23:59'	System	08 Aug 2020 13:01:15

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '05 Oct 2020 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '09 Oct 2020 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '12 Oct 2020 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '16 Oct 2020 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '19 Oct 2020 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '23 Oct 2020 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '26 Oct 2020 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '30 Oct 2020 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '02 Nov 2020 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '06 Nov 2020 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '09 Nov 2020 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '13 Nov 2020 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-19T16:48:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0446a28a-962e-48e6-b68f-f3c873349a5b' User entered 'No (N)'	System	19 Nov 2020 21:48:34
	System	19 Nov 2020 21:48:34

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-19T16:48:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0446a28a-962e-48e6-b68f-f3c873349a5b' User entered 'No (N)'	System	19 Nov 2020 21:48:34

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-19T16:48:31', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0446a28a-962e-48e6-b68f-f3c873349a5b' User entered '19 Nov 2020 16:48:31'	System	19 Nov 2020 21:48:34
	System	19 Nov 2020 21:48:34

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 16:26:47

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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 16:26:47
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

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Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 16:26:47

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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 16:26:47
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 16:26:47

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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 16:26:47
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 16:26:47

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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 16:26:47
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

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Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:26:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 16:26:47

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:26:47
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 16:26:47

US3402284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	11 Nov 2020 12:50:03
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	11 Nov 2020 12:49:42
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	03 Nov 2020 15:50:09

US3402284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:49:42
User entered '3 Nov 2020'	Tammy Kohn (b) (4)	03 Nov 2020 15:50:09

US3402284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	11 Nov 2020 12:50:03
User entered empty; reason for change Data Entry Error	Traci Hull (b) (4) (b) (4)	11 Nov 2020 12:49:42
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	03 Nov 2020 15:50:09

US3402284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	03 Nov 2020 15:50:09

US3402284

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	03 Nov 2020 15:50:12

US3402284

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:59

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 15:50:12

US3402284

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:25:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:33:28
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4)	24 Sep 2020 20:31:47
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 20:43:05
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:41
User entered 'USA-US059-2020-mRNA-1273-P301000004'	System	25 Sep 2020 15:16:36
User entered 'New'	(b) (4), (b) (6)	25 Sep 2020 15:16:36

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stone - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 20:39:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 20:39:44
	(b) (4)	
Data point term sent to Coder	System	24 Sep 2020 20:38:18
User entered 'Kidney Stone'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered 'No (N)'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered 'No (N)'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered '22 Sep 2020'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	12 Oct 2020 13:02:44
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	12 Oct 2020 13:02:44
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Sep 2020 20:37:45
User entered '08:00'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 13:02:44
User entered '22 Sep 2020 08:00'	System	24 Sep 2020 20:37:45

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered 'No (N)'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered '23 Sep 2020'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	12 Oct 2020 13:02:44
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	12 Oct 2020 13:02:44
	(b) (4)	
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	24 Sep 2020 20:37:45
User entered '11:30'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 13:02:44
User entered '23 Sep 2020 11:30'	System	24 Sep 2020 20:37:45

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered '0'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered '0'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered '1'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered '22 Sep 2020'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered '23 Sep 2020'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered 'No (N)'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered empty.	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered '0'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered '0'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered '0'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User closed query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 10 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 13:01:18
Query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 10 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'DATA UPDATED' (Site from Safety).	Tammy Kohn (b) (4)	12 Oct 2020 13:05:01
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	12 Oct 2020 13:04:55
User opened query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 10 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:42:59
User entered 'None (NONE)'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered '0'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User closed query 'Per DM CLR: Please review Other Action Taken and please note that there are recorded medications indicated for this AE. However, ConMed is not listed as Other Action Taken. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Please review Other Action Taken and please note that there are recorded medications indicated for this AE. However, ConMed is not listed as Other Action Taken. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:52:08
Query 'Per DM CLR: Please review Other Action Taken and please note that there are recorded medications indicated for this AE. However, ConMed is not listed as Other Action Taken. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4)	29 Oct 2020 21:45:44
	(b) (4)	
User entered '1' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	29 Oct 2020 21:45:33
	(b) (4)	
User opened query 'Per DM CLR: Please review Other Action Taken and please note that there are recorded medications indicated for this AE. However, ConMed is not listed as Other Action Taken. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM). User entered '0'	(b) (4), (b) (6)	28 Oct 2020 14:15:58
	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered '1'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User entered empty.	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45
	(b) (4)	

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:18
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:19
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:30:10
User closed query 'Per DM CLR: SAE Narrative indicates that the subject underwent CT Scan of Abdomen and Pelvis and it appears that the subject had a Complete Blood Count. However, there are not recorded Concomitant Procedures that match these information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: SAE Narrative indicates that the subject underwent CT Scan of Abdomen and Pelvis and it appears that the subject had a Complete Blood Count. However, there are not recorded Concomitant Procedures that match these information. Please update to record the procedures as appropriate. Otherwise, clarify.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:31:27
User opened query 'Per DM CLR: SAE Narrative indicates that the subject underwent CT Scan of Abdomen and Pelvis and it appears that the subject had a Complete Blood Count. However, there are not recorded Concomitant Procedures that match these information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	Jennifer Molstead (b) (4)	29 Oct 2020 21:45:43
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 14:03:24

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 14:03:20
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	14 Oct 2020 14:03:18
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'UPDATED' (Site from Safety).	Jennifer Molstead (b) (4)	13 Oct 2020 22:14:59
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)	13 Oct 2020 22:14:53
User entered 'SUBJECT HAD SEVERE PAIN THE MORNING OF 22SEP2020. HE WENT TO THE ER AND WAS ADMITTED FOR EMERGENCY LITHOTRIPSY. PROCEDURE WITH STENT PLACEMENT WAS PERFORMED. SUBJECT WAS KEPT OVER NIGHT AND DISCHARGED 23SEP2020 AT 11:30. SUBJECT HAD A WHITE BLOOD COUNT OF 15.1UL, NORMAL IS 10.3 UL, CT ABDOMEN AND PELVIS: LEFT OBSTRUCTIVE UROPATHY DUE TO 4.5MM DISTAL URETERAL STONE. SUBJECT WAS GIVEN CEFTRIAXONE 1G IV DAILY, HEPARIN 5,000 UNITS Q12H, KETOROLAC 30MG IV Q6H, TAMSULOSIN 0.4 MG PO DAILY. SUBJECT WAS ALSO GIVEN SODIUM CHLORIDE 0.9% 100ML/HR. COVID-19 TESTING WAS PREFORMED 22SEP2020 RESULT WAS NEGATIVE.' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	13 Oct 2020 22:14:47

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAD SEVERE PAIN THE MORNING OF 22SEP2020. HE WENT TO THE ER AND WAS ADMITTED FOR EMERGENCY LITHOTRIPSY. PROCEDURE WITH STENT PLACEMENT WAS PERFORMED. SUBJECT WAS KEPT OVER NIGHT AND DISCHARGED 23SEP2020 AT 11:30. SUBJECT HAD A WHITE BLOOD COUNT OF 15.1UL, NORMAL IS 10.3 UL, CT ABDOMEN AND PELVIS: LEFT OBSTRUCTIVE UROPATHY DUE TO 4.5MM DISTAL URETERAL STONE. SUBJECT WAS GIVEN CEFTRIAZONE 1G IV DAILY, HEPARIN 5,000 UNITS Q12H, KETOROLAC 30MG IV Q6H, TAMSULOSIN 0.4 MG PO DAILY. SUBJECT WAS ALSO GIVEN SODIUM CHLORIDE 0.9% 100ML/HR. COVID-19 TESTING WAS PREFORMED RESULT WAS NEGATIVE.' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	13 Oct 2020 22:14:16
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'UPDATED' (Site from Safety).	Jennifer Molstead (b) (4)	13 Oct 2020 22:13:21
User entered 'SUBJECT HAD SEVERE PAIN THE MORNING OF 22SEP2020. HE WENT TO THE ER AND WAS ADMITTED FOR EMERGENCY LITHOTRIPSY. PROCEDURE WITH STENT PLACEMENT WAS PERFORMED. SUBJECT WAS KEPT OVER NIGHT AND DISCHARGED 23SEP2020 AT 11:30. SUBJECT HAD A WHITE BLOOD COUNT OF 15.1uL, NORMAL IS 10.3 uL, CT ABDOMEN AND PELVIS: LEFT OBSTRUCTIVE UROPATHY DUE TO 4.5MM DISTAL URETERAL STONE. SUBJECT WAS GIVEN CEFTRIAZONE 1g IV DAILY, HEPARIN 5,000 UNITS Q12H, KETOROLAC 30MG IV Q6H, TAMSULOSIN 0.4 MG PO DAILY. SUBJECT WAS ALSO GIVEN SODIUM CHLORIDE 0.9% 100ML/HR.' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	13 Oct 2020 22:13:02

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:42:36
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)	02 Oct 2020 17:42:26
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:42:01
User entered 'Subject had severe pain the morning of 22Sep2020. He went to the ER and was admitted for emergency lithotripsy. Procedure was performed subject was kept over night and discharged 23Sep2020 at 11:30. Awaiting medical records for update of medications given.'	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:45

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 20:37:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 20:37:45

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Sep 2020 20:37:45

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:25:59

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:34:46
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 20:43:21
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:01:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 19:01:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS WITH MINERALS, PRODUCT: ASCORBIC ACID;CALCIUM;MINERALS NOS;RETINOL;TOCOPHERYL ACETATE;VITAMIN B NOS;VITAMINS NOS;ZINC, PRODUCTSYNONYM: CENTRUM SILVER [ASCORBIC ACID;CALCIUM;MINERALS NOS;RETINOL;TOCOPHERYL ACETATE;VITAMIN B NOS;VITAMINS NOS;ZINC] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 05:30:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 05:30:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:06:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:06:10
Data point term sent to Coder	System	09 Aug 2020 13:45:34
v6.020 DTW (1102)		2036 of 2426

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Tarin Gordon (b) (4)	09 Aug 2020 13:44:50
User entered 'MULTIVITAMIN (CENTRUM SILVER)' reason for change: Data Entry Error	Tarin Gordon (b) (4)	09 Aug 2020 13:44:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Aug 2020 20:45:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Aug 2020 20:45:51
Data point term sent to Coder	System	08 Aug 2020 20:45:11
User entered 'CENTRUM SILVER'	Traci Hull (b) (4)	08 Aug 2020 20:44:17

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 20:44:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'DIETARY SUPPLEMENT'	Traci Hull (b) (4)	08 Aug 2020 20:44:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '1' reason for change: Data Entry Error	Tarin Gordon (b) (4)	09 Aug 2020 13:44:50
	(b) (4)	
User entered '1000'	Traci Hull (b) (4)	08 Aug 2020 20:44:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'tablet (TABLET)' reason for change:	Tarin Gordon (b) (4)	09 Aug 2020 13:44:50
Data Entry Error	(b) (4)	
User entered 'mg (mg)'	Traci Hull (b) (4)	08 Aug 2020 20:44:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:44:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'once daily (QD)'	Traci Hull (b) (4)	08 Aug 2020 20:44:17
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:44:17
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	08 Aug 2020 20:44:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:44:17
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
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)	15 Aug 2020 17:40:07
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 'ON GOING' (Site from System).	Traci Hull (b) (4)	08 Aug 2020 20:47:34
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	08 Aug 2020 20:44:17
User entered 'UN UNK 2000'	Traci Hull (b) (4)	08 Aug 2020 20:44:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 20:44:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 20:44:17
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:44:17
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 20:44:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:44:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:44:17

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Aug 2020 20:44:17

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:06:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:06:01
Data point term sent to Coder Coding entries removed.	System Traci Hull (b) (4) (b) (4)	08 Oct 2020 20:40:09 08 Oct 2020 20:39:23
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 14:06:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 14:06:48
Data point term sent to Coder	System	10 Sep 2020 13:18:11
Data point term sent to Coder	System	10 Sep 2020 13:17:10
Coding entries removed.	Tammy Kohn (b) (4) (b) (4)	10 Sep 2020 13:16:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Aug 2020 14:01:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Aug 2020 14:01:29
Data point term sent to Coder	System	09 Aug 2020 14:00:39
Data point term sent to Coder	System	08 Aug 2020 20:45:11
User entered 'ASPIRIN'	Traci Hull (b) (4)	08 Aug 2020 20:44:51

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User closed query 'Per CDM: Indication has been updated to Cardiac Prophylaxis however response to Prophylaxis is NO. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:00:59
Query 'Per CDM: Indication has been updated to Cardiac Prophylaxis however response to Prophylaxis is NO. Please review and update as appropriate.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	20 Oct 2020 13:42:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	20 Oct 2020 13:42:48
User opened query 'Per CDM: Indication has been updated to Cardiac Prophylaxis however response to Prophylaxis is NO. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 14:45:37
User closed query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prohylaxis. Please review, reconcile, and update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 15:14:28
Query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prohylaxis. Please review, reconcile, and update accordingly.' answered with 'Prevent Heart Attack.' (Site from DM).	Tammy Kohn (b) (4)	10 Sep 2020 13:14:33
User opened query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prohylaxis. Please review, reconcile, and update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 11:10:08
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 20:44:51

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 14:45:29
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4) (b) (4)	08 Oct 2020 20:39:31
User entered 'CARDIAC PROPHYLAXIS' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	08 Oct 2020 20:39:23
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 04:38:11
User entered 'CARDIAC EVENT' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	10 Sep 2020 13:17:11
User entered 'Prevent cardiac event' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	10 Sep 2020 13:16:30
User entered 'CARDIAC PROPHYLAXIS' reason for change: Data Entry Error	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 13:59:47
User entered 'BLOOD THINNER'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:44:51

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '81'	Traci Hull (b) (4)	08 Aug 2020 20:44:51
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'mg (mg)'	Traci Hull (b) (4)	08 Aug 2020 20:44:51
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:44:51
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'once daily (QD)'	Traci Hull (b) (4)	08 Aug 2020 20:44:51
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:44:51
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	08 Aug 2020 20:44:51
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:44:51
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
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)	15 Aug 2020 17:40:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Traci Hull (b) (4)	08 Aug 2020 20:47:27
answered with 'ON GOING' (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	08 Aug 2020 20:44:51
User entered 'UN UNK 2000'	Traci Hull (b) (4)	08 Aug 2020 20:44:51
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 20:44:51
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 20:44:51
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:44:51
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 20:44:51
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:44:51

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:44:51

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Aug 2020 20:44:51

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Aug 2020 20:46:51
	(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 Aug 2020 20:46:51
	(b) (4)	
Data point term sent to Coder	System	08 Aug 2020 20:46:11
User entered 'METFORMIN'	Traci Hull (b) (4)	08 Aug 2020 20:45:29
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 20:45:29
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'TYPE 2 DIABETES'	Traci Hull (b) (4)	08 Aug 2020 20:45:29
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '500'	Traci Hull (b) (4)	08 Aug 2020 20:45:29
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'mg (mg)'	Traci Hull (b) (4)	08 Aug 2020 20:45:29
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:45:29
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'once daily (QD)'	Traci Hull (b) (4)	08 Aug 2020 20:45:29
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:45:29
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	08 Aug 2020 20:45:29
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:45:29
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
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)	15 Aug 2020 17:40:16
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 'ON GOING' (Site from System).	Traci Hull (b) (4)	08 Aug 2020 20:47:19
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	08 Aug 2020 20:45:29
User entered 'UN UNK 2019'	Traci Hull (b) (4)	08 Aug 2020 20:45:29

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 20:45:29
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 20:45:29
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:45:29
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 20:45:29
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:45:29

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:45:29

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Aug 2020 20:45:29

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:46:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:46:51
Data point term sent to Coder	System	08 Aug 2020 20:46:12
User entered 'METOPROLOL'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:46:06

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 20:46:06
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'HYPERTENSION'	Traci Hull (b) (4)	08 Aug 2020 20:46:06
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '100'	Traci Hull (b) (4)	08 Aug 2020 20:46:06
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'mg (mg)'	Traci Hull (b) (4)	08 Aug 2020 20:46:06
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:46:06
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'once daily (QD)'	Traci Hull (b) (4)	08 Aug 2020 20:46:06
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:46:06
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	08 Aug 2020 20:46:06
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:46:06
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 18:21:14
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	26 Sep 2020 15:02:01
User entered 'UN UNK 2017' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	26 Sep 2020 15:01:46
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 02:11:15
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)	15 Aug 2020 17:40:20
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 'ON GOING' (Site from System).	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:47:13
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	08 Aug 2020 20:46:06
User entered 'UN UNK 2010'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:46:06

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 20:46:06
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 20:46:06
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:46:06
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 20:46:06
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:46:06

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:46:06

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Aug 2020 20:46:06

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
Query 'Per source please verify and update if this is used as a combo drug with Hydrochlorothiazide, 12.5mg. ' canceled (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 20:38:57
User opened query 'Per source please verify and update if this is used as a combo drug with Hydrochlorothiazide, 12.5mg. ' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 20:37:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: BENAZEPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 15:06:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 15:06:43
Data point term sent to Coder Coding entries removed.	System Tammy Kohn (b) (4)	26 Sep 2020 15:05:19 26 Sep 2020 15:04:32
User entered 'BENAZEPRIL' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	26 Sep 2020 15:04:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND DIURETICS, PRODUCT: BENAZEPRIL;HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 06:50:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 06:50:32
Data point term sent to Coder User entered 'BENAZEPRIL/ HYDROCHLOROTHIAZIDE' reason for change: Data Entry Error	System Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 13:58:38 09 Aug 2020 13:58:31
Data point term sent to Coder User entered 'BIZNAZPRIL HYDROCHLOROTHIAZIDE'	System Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:47:13 08 Aug 2020 20:46:40

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 20:46:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'HYPERTENSION'	Traci Hull (b) (4)	08 Aug 2020 20:46:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '20' reason for change: Data Entry Error	Tammy Kohn (b) (4)	26 Sep 2020 15:04:32
	(b) (4)	
User entered '20/12.5' reason for change: Data Entry Error	Tarin Gordon (b) (4)	09 Aug 2020 13:58:31
	(b) (4)	
User entered '20'	Traci Hull (b) (4)	08 Aug 2020 20:46:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'mg (mg)'	Traci Hull (b) (4)	08 Aug 2020 20:46:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:46:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'once daily (QD)'	Traci Hull (b) (4)	08 Aug 2020 20:46:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:46:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	08 Aug 2020 20:46:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:46:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 18:21:45
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	26 Sep 2020 15:07:15
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 02:10:22
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)	15 Aug 2020 17:40:27
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ON GOING' (Site from System).	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:47:05
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	08 Aug 2020 20:46:40
User entered 'UN UNK 2000'	Traci Hull (b) (4) (b) (4)	08 Aug 2020 20:46:40

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '0'	Traci Hull (b) (4)	08 Aug 2020 20:46:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Yes (Y)'	Traci Hull (b) (4)	08 Aug 2020 20:46:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	08 Aug 2020 20:46:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 20:46:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:46:40

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Aug 2020 20:46:40

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Aug 2020 20:46:40

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 03:46:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 03:46:55
Data point term sent to Coder Coding entries removed.	System Tammy Kohn (b) (4) (b) (4)	26 Sep 2020 15:03:16 26 Sep 2020 15:02:41
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 14:03:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 14:03:31
Data point term sent to Coder User entered 'NAPROXEN'	System Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 14:02:39 09 Aug 2020 14:01:56

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 14:01:56
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User closed query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS (e.g., Generalized, Both Knees, Right Hip, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:56:28
User entered 'OSTEOARTHRITIS LEFT HIP' reason for change: Data Entry Error	Tammy Kohn (b) (4)	26 Sep 2020 15:02:41
Query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS (e.g., Generalized, Both Knees, Right Hip, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'LEFT HIP' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS (e.g., Generalized, Both Knees, Right Hip, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	Tammy Kohn (b) (4)	26 Sep 2020 15:02:27
User entered 'OSTEOARTHRITIS'	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 02:11:54
	Tarin Gordon (b) (4)	09 Aug 2020 14:01:56
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '500'	Tarin Gordon (b) (4)	09 Aug 2020 14:01:56
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'mg (mg)'	Tarin Gordon (b) (4)	09 Aug 2020 14:01:56
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:01:56
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	09 Aug 2020 14:01:56
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:01:56
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	09 Aug 2020 14:01:56
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:01:56
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
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)	15 Aug 2020 17:40:32
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)	09 Aug 2020 14:23:15
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	09 Aug 2020 14:01:56
User entered 'UN UNK 1982'	Tarin Gordon (b) (4)	09 Aug 2020 14:01:56
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 14:01:56
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	09 Aug 2020 14:01:56
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:01:56
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 14:01:56
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 14:01:56

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 14:01:56

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 14:01:56

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 11:35:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 11:35:07
Data point term sent to Coder	System	09 Aug 2020 14:03:40
User entered 'CYCLOBENZAPRINE'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 14:02:40

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 14:02:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'PINCHED NERVE LEFT SHOULDER'	Tarin Gordon (b) (4)	09 Aug 2020 14:02:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '10'	Tarin Gordon (b) (4)	09 Aug 2020 14:02:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'mg (mg)'	Tarin Gordon (b) (4)	09 Aug 2020 14:02:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:02:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	09 Aug 2020 14:02:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:02:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	09 Aug 2020 14:02:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:02:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
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)	15 Aug 2020 17:40:35
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)	09 Aug 2020 14:23:07
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	09 Aug 2020 14:02:40
User entered 'UN Feb 2020'	Tarin Gordon (b) (4)	09 Aug 2020 14:02:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 14:02:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	09 Aug 2020 14:02:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:02:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 14:02:40
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 14:02:40

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 14:02:40

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 14:02:40

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 14:04:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 14:04:31
Data point term sent to Coder	System	09 Aug 2020 14:03:40
User entered 'ATORVASTATIN CALCIUM'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 14:03:17

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'HYPERCHOLESTEROLEMIA'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '10'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'mg (mg)'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:03:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:03:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:03:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
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)	15 Aug 2020 17:40:43
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)	09 Aug 2020 14:23:02
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	09 Aug 2020 14:03:17
User entered 'UN May 2020'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:17

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:03:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 14:03:17

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 14:03:17

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 14:03:17

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 14:05:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Aug 2020 14:05:31
Data point term sent to Coder	System	09 Aug 2020 14:04:40
User entered 'ALLOPURINOL'	Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 14:03:46

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:46
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User closed query 'Per DM CLR: Please update the indication to reflect the location of GOUT (e.g., Generalized, Both Hips, Right Knee, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 17:40:30
Query 'Per DM CLR: Please update the indication to reflect the location of GOUT (e.g., Generalized, Both Hips, Right Knee, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'RIGHT FOOT' (Site from DM).	Tammy Kohn (b) (4)	26 Sep 2020 15:12:39
User opened query 'Per DM CLR: Please update the indication to reflect the location of GOUT (e.g., Generalized, Both Hips, Right Knee, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 02:09:02
User entered 'GOUT'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:46

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '300'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:46
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'mg (mg)'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:46
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:03:46
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:46
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:03:46
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:46
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:03:46
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
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)	15 Aug 2020 17:40:47
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)	09 Aug 2020 14:22:56
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	09 Aug 2020 14:03:46
User entered 'UN UNK 2005'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:46

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:46
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:46
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:03:46
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 14:03:46
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 14:03:46

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 14:03:46

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 14:03:46

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 14:36:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 14:36:40
Data point term sent to Coder Coding entries removed.	System Tammy Kohn (b) (4) (b) (4)	10 Sep 2020 13:29:34 10 Sep 2020 13:29:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE PROPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:47:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 06:47:14
Data point term sent to Coder User entered 'FLUTICASONE PROPIONATE'	System Tarin Gordon (b) (4) (b) (4)	09 Aug 2020 14:05:41 09 Aug 2020 14:04:58

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 14:04:58
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'SLEEP APNEA'	Tarin Gordon (b) (4)	09 Aug 2020 14:04:58
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '50'	Tarin Gordon (b) (4)	09 Aug 2020 14:04:58
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'ug (ug)'	Tarin Gordon (b) (4)	09 Aug 2020 14:04:58
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:04:58
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'once daily (QD)' reason for change:	Tarin Gordon (b) (4)	09 Aug 2020 14:22:49
Data Entry Error	(b) (4)	
User entered 'as needed (PRN)'	Tarin Gordon (b) (4)	09 Aug 2020 14:04:58
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:04:58
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User closed query 'Per MM, route of administration is oral. Please review and update route of administration, as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 15:14:55
Query 'Per MM, route of administration is oral. Please review and update route of administration, as appropriate.' answered with 'Data updated' (Site from DM).	Tammy Kohn (b) (4)	10 Sep 2020 13:29:36
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	(b) (4)	10 Sep 2020 13:29:28
User opened query 'Per MM, route of administration is oral. Please review and update route of administration, as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:19:39
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	09 Aug 2020 14:04:58

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:04:58
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
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)	15 Aug 2020 17:40:51
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)	09 Aug 2020 14:22:21
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	09 Aug 2020 14:04:58
User entered 'UN UNK 2016'	Tarin Gordon (b) (4)	09 Aug 2020 14:04:58
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '0'	Tarin Gordon (b) (4)	09 Aug 2020 14:04:58
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	09 Aug 2020 14:04:58
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tarin Gordon (b) (4)	09 Aug 2020 14:04:58
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Tarin Gordon (b) (4)	09 Aug 2020 14:04:58
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 14:22:49
User entered empty.	System	09 Aug 2020 14:04:58

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Aug 2020 14:22:49
User entered empty.	System	09 Aug 2020 14:04:58

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Aug 2020 14:22:49
User entered empty.	System	09 Aug 2020 14:04:58

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:04:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 23:04:38
Data point term sent to Coder Coding entries removed.	System Tammy Kohn (b) (4)	20 Oct 2020 13:44:13 20 Oct 2020 13:43:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 19:00:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 19:00:44
Data point term sent to Coder User entered 'IBUPROFEN'	System Traci Hull (b) (4) (b) (4)	17 Sep 2020 19:00:04 17 Sep 2020 18:59:47

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Traci Hull (b) (4)	17 Sep 2020 18:59:47
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE AND JOINT ACHES 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, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:01:11
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE AND JOINT ACHES 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, clarify.' answered with 'DATA UPDATED NOT AN AE OR SAE OR MAAE' (Site from DM).	Tammy Kohn (b) (4)	20 Oct 2020 13:43:33
User entered 'MILD MUSCLE AND JOINT ACHES' reason for change: Data Entry Error	(b) (4)	20 Oct 2020 13:43:20
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 MUSCLE AND JOINT ACHES 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, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 09:31:42
User entered 'MUSCLE AND JOINT ACHES'	Traci Hull (b) (4)	17 Sep 2020 18:59:47

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '200'	Traci Hull (b) (4)	17 Sep 2020 18:59:47
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'mg (mg)'	Traci Hull (b) (4)	17 Sep 2020 18:59:47
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	17 Sep 2020 18:59:47
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'as needed (PRN)'	Traci Hull (b) (4)	17 Sep 2020 18:59:47
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	17 Sep 2020 18:59:47
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	17 Sep 2020 18:59:47
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Traci Hull (b) (4)	17 Sep 2020 18:59:47
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '13 Sep 2020'	Traci Hull (b) (4)	17 Sep 2020 18:59:47
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '0'	Traci Hull (b) (4)	17 Sep 2020 18:59:47
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Traci Hull (b) (4)	17 Sep 2020 18:59:47
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '14 Sep 2020'	Traci Hull (b) (4)	17 Sep 2020 18:59:47
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Yes (Y)'	Traci Hull (b) (4)	17 Sep 2020 18:59:47
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 18:59:47

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 18:59:47

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 18:59:47

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 15:07:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 15:07:44
Data point term sent to Coder	System	26 Sep 2020 15:06:21
User entered 'HYDROCHLOROTHIAZIDE'	Tammy Kohn (b) (4) (b) (4)	26 Sep 2020 15:05:53

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Tammy Kohn (b) (4)	26 Sep 2020 15:05:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'HYPERTENSION'	Tammy Kohn (b) (4)	26 Sep 2020 15:05:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '12.5'	Tammy Kohn (b) (4)	26 Sep 2020 15:05:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'mg (mg)'	Tammy Kohn (b) (4)	26 Sep 2020 15:05:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tammy Kohn (b) (4)	26 Sep 2020 15:05:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'once daily (QD)'	Tammy Kohn (b) (4)	26 Sep 2020 15:05:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tammy Kohn (b) (4)	26 Sep 2020 15:05:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4)	26 Sep 2020 15:05:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tammy Kohn (b) (4)	26 Sep 2020 15:05:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'UN UNK 2000'	Tammy Kohn (b) (4)	26 Sep 2020 15:05:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '0'	Tammy Kohn (b) (4)	26 Sep 2020 15:05:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	26 Sep 2020 15:05:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Tammy Kohn (b) (4)	26 Sep 2020 15:05:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Sep 2020 15:05:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Sep 2020 15:05:59
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	26 Sep 2020 15:05:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Sep 2020 15:05:53
User entered empty.	Tammy Kohn (b) (4)	26 Sep 2020 15:05:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:05:53

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 15:05:53

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 15:05:53

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 23:30:25
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 23:30:25
	(b) (4)	
Data point term sent to Coder	System	13 Oct 2020 22:17:43
User entered 'CEFTRIAXONE'	Jennifer Molstead (b) (4)	13 Oct 2020 22:16:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:16:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'KIDNEY STONE'	Jennifer Molstead (b) (4)	13 Oct 2020 22:16:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '1'	Jennifer Molstead (b) (4)	13 Oct 2020 22:16:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'g (g)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:16:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Jennifer Molstead (b) (4)	13 Oct 2020 22:16:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:16:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Jennifer Molstead (b) (4)	13 Oct 2020 22:16:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:16:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Jennifer Molstead (b) (4)	13 Oct 2020 22:16:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '23 Sep 2020'	Jennifer Molstead (b) (4)	13 Oct 2020 22:16:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '0'	Jennifer Molstead (b) (4)	13 Oct 2020 22:16:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.	Traci Hull (b) (4)	17 Nov 2020 15:53:52
' answered with 'correct as is' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.	(b) (4), (b) (6)	16 Nov 2020 07:47:53
' (Site from DM).		
Query 'v' canceled (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 07:47:50
User opened query 'v' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 07:47:48
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:16:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Jennifer Molstead (b) (4)	13 Oct 2020 22:16:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:16:53
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 22:16:53

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 22:16:53

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 22:16:53

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:03:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:03:22
Data point term sent to Coder	System	13 Oct 2020 22:18:43
User entered 'HEPARIN'	Jennifer Molstead (b) (4) (b) (4)	13 Oct 2020 22:18:34

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if the response should be updated to 'No' as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update response as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 06:24:27
Query 'Per DM CLR: Prophylaxis = Yes. Please review if the response should be updated to 'No' as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update response as appropriate. ' answered with 'updated' (Site from DM).	Traci Hull (b) (4)	17 Nov 2020 15:54:27
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4)	17 Nov 2020 15:54:19
User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if the response should be updated to 'No' as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update response as appropriate. ' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 07:49:18
	Jennifer Molstead (b) (4)	13 Oct 2020 22:18:34

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'KIDNEY STONE'	Jennifer Molstead (b) (4)	13 Oct 2020 22:18:34
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '5000'	Jennifer Molstead (b) (4)	13 Oct 2020 22:18:34
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'IU (IU)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:18:34
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Jennifer Molstead (b) (4)	13 Oct 2020 22:18:34
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'twice daily (BID)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:18:34
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Jennifer Molstead (b) (4)	13 Oct 2020 22:18:34
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:18:34
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Jennifer Molstead (b) (4)	13 Oct 2020 22:18:34
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '22 Sep 2020'	Jennifer Molstead (b) (4)	13 Oct 2020 22:18:34
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '0'	Jennifer Molstead (b) (4)	13 Oct 2020 22:18:34
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:18:34
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '23 Sep 2020'	Jennifer Molstead (b) (4)	13 Oct 2020 22:18:34
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:18:34
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Oct 2020 22:18:34

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 22:18:34

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 22:18:34

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:51:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:51:23
Data point term sent to Coder	System	13 Oct 2020 22:19:46
User entered 'KETOROLAC'	Jennifer Molstead (b) (4) (b) (4)	13 Oct 2020 22:19:36

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:19:36
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'KIDNEY STONE'	Jennifer Molstead (b) (4)	13 Oct 2020 22:19:36
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '30'	Jennifer Molstead (b) (4)	13 Oct 2020 22:19:36
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:19:36
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Jennifer Molstead (b) (4)	13 Oct 2020 22:19:36
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'four times daily (QID)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:19:36
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Jennifer Molstead (b) (4)	13 Oct 2020 22:19:36
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:19:36
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Jennifer Molstead (b) (4)	13 Oct 2020 22:19:36
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '22 Sep 2020'	Jennifer Molstead (b) (4)	13 Oct 2020 22:19:36
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '0'	Jennifer Molstead (b) (4)	13 Oct 2020 22:19:36
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:19:36
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '23 Sep 2020'	Jennifer Molstead (b) (4)	13 Oct 2020 22:19:36
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:19:36
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	13 Oct 2020 22:19:36

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 22:19:36

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 22:19:36

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 05:17:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	14 Oct 2020 05:17:30
Data point term sent to Coder	System	13 Oct 2020 22:20:47
User entered 'TAMSULOSIN'	Jennifer Molstead (b) (4)	13 Oct 2020 22:20:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:20:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'KIDNEY STONE'	Jennifer Molstead (b) (4)	13 Oct 2020 22:20:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '0.4'	Jennifer Molstead (b) (4)	13 Oct 2020 22:20:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:20:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Jennifer Molstead (b) (4)	13 Oct 2020 22:20:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:20:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Jennifer Molstead (b) (4)	13 Oct 2020 22:20:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:20:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Jennifer Molstead (b) (4)	13 Oct 2020 22:20:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '23 Sep 2020'	Jennifer Molstead (b) (4)	13 Oct 2020 22:20:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered '0'	Jennifer Molstead (b) (4)	13 Oct 2020 22:20:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.	Traci Hull (b) (4)	17 Nov 2020 15:54:59
' answered with 'correct as is' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.	(b) (4), (b) (6)	16 Nov 2020 07:52:27
' (Site from DM).		
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:20:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered empty.	Jennifer Molstead (b) (4)	13 Oct 2020 22:20:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:36
User entered 'No (N)'	Jennifer Molstead (b) (4)	13 Oct 2020 22:20:17
	(b) (4)	

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 22:20:17

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 22:20:17

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 22:20:17

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:25:59

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:40:51
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4)	24 Sep 2020 20:37:59
User entered 'No (N)'	Traci Hull (b) (4)	08 Aug 2020 20:43:14
	(b) (4)	

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:25:59

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:32:51
User entered '22 Sep 2020'	Jennifer Molstead (b) (4)	24 Sep 2020 20:38:56
	(b) (4)	

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:25:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:32:51
User entered 'Lithotripsy'	Jennifer Molstead (b) (4)	24 Sep 2020 20:38:56
	(b) (4)	

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:25:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:32:51
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4)	24 Sep 2020 20:38:56
	(b) (4)	

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:25:59

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:32:51
User entered empty.	Jennifer Molstead (b) (4)	24 Sep 2020 20:38:56
	(b) (4)	

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:25:59

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:32:51
User entered '22 Sep 2020'	Jennifer Molstead (b) (4)	29 Oct 2020 21:41:54
	(b) (4)	

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:25:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:32:51
User entered 'CT OF ABDOMEN AND PELVIS'	Jennifer Molstead (b) (4)	29 Oct 2020 21:43:02
reason for change: New Information	(b) (4)	
User entered 'Ultrasound of Abdomen and Pelvis'	Jennifer Molstead (b) (4)	29 Oct 2020 21:41:54
	(b) (4)	

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:25:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:32:51
User entered 'Adverse Event (AE)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	29 Oct 2020 21:44:20
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	(b) (4)	
	System	29 Oct 2020 21:43:02
User entered 'Other (OTHER)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	29 Oct 2020 21:43:02
	(b) (4)	
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	29 Oct 2020 21:41:54
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4)	29 Oct 2020 21:41:54
	(b) (4)	

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:25:59

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:32:51
User entered empty; reason for change Data Entry Error	Jennifer Molstead (b) (4)	29 Oct 2020 21:44:20
	(b) (4)	
User entered 'Positive for Kidney Stones'	Jennifer Molstead (b) (4)	29 Oct 2020 21:41:54
	(b) (4)	

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:25:59

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:32:51
User entered '22 Sep 2020'	Jennifer Molstead (b) (4)	29 Oct 2020 21:43:52
	(b) (4)	

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:25:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:32:51
User entered 'Complete Blood Count'	Jennifer Molstead (b) (4)	29 Oct 2020 21:43:52
	(b) (4)	

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:25:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:32:51
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	29 Oct 2020 21:44:08
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	29 Oct 2020 21:44:08
	(b) (4)	
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	29 Oct 2020 21:43:52
User entered 'Diagnostic (DIAGNOSTIC)'	Jennifer Molstead (b) (4)	29 Oct 2020 21:43:52
	(b) (4)	

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 09:25:59

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:32:51
User entered empty; reason for change Data Entry Error	Jennifer Molstead (b) (4)	29 Oct 2020 21:44:08
User entered 'Elevated White count'	Jennifer Molstead (b) (4)	29 Oct 2020 21:43:52

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'USA-US059-2020-MRNA-1273-P301000004'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Yes (Y)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Yes (Y)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Frank'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Eder'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered '1290 Upper Front Street'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Binghamton'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'NY'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered '13901'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:01:35
User entered 'US'	System	25 Sep 2020 15:17:05

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Oct 2020 14:36:18
User entered '3'	System	14 Oct 2020 14:03:44
User entered '2'	System	13 Oct 2020 13:01:46
User entered '1'	System	25 Sep 2020 15:17:05

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'USA-US059-2020-MRNA-1273-P301000004'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Yes (Y)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Yes (Y)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Frank'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Eder'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered '1290 Upper Front Street'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Binghamton'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'NY'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered '13901'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:01:35
User entered 'US'	System	25 Sep 2020 15:17:05

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Oct 2020 14:36:18
User entered '3'	System	14 Oct 2020 14:03:44
User entered '2'	System	13 Oct 2020 13:01:46
User entered '1'	System	25 Sep 2020 15:17:05

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:25:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
User entered '25/Sep/2020 15:17'	System	25 Sep 2020 15:17:05

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:25:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:01:35
User entered '1'	(b) (4), (b) (6)	25 Sep 2020 15:17:05

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'USA-US059-2020-MRNA-1273-P301000004'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Yes (Y)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Yes (Y)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Frank'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Eder'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered '1290 Upper Front Street'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Binghamton'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'NY'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered '13901'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:01:35
User entered 'US'	System	25 Sep 2020 15:17:05

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Oct 2020 14:36:18
User entered '3'	System	14 Oct 2020 14:03:44
User entered '2'	System	13 Oct 2020 13:01:46
User entered '1'	System	25 Sep 2020 15:17:05

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:25:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
User entered '13/Oct/2020 13:01'	System	13 Oct 2020 13:01:46

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:25:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 14:03:34
User entered '1'	(b) (4), (b) (6)	13 Oct 2020 13:01:46

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'USA-US059-2020-MRNA-1273-P301000004'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Yes (Y)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Yes (Y)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Frank'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Eder'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered '1290 Upper Front Street'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Binghamton'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'NY'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered '13901'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:01:35
User entered 'US'	System	25 Sep 2020 15:17:05

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Oct 2020 14:36:18
User entered '3'	System	14 Oct 2020 14:03:44
User entered '2'	System	13 Oct 2020 13:01:46
User entered '1'	System	25 Sep 2020 15:17:05

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:25:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
User entered '14/Oct/2020 10:03'	System	14 Oct 2020 14:03:44

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:25:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	30 Oct 2020 14:36:10
User entered '1'	(b) (4), (b) (6)	14 Oct 2020 14:03:44

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'USA-US059-2020-MRNA-1273-P301000004'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Yes (Y)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Yes (Y)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'No (N)'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Frank'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Eder'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered '1290 Upper Front Street'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'Binghamton'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered 'NY'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:16:58
User entered '13901'	System	25 Sep 2020 15:16:36

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:01:35
User entered 'US'	System	25 Sep 2020 15:17:05

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Oct 2020 14:36:18
User entered '3'	System	14 Oct 2020 14:03:44
User entered '2'	System	13 Oct 2020 13:01:46
User entered '1'	System	25 Sep 2020 15:17:05

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:25:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
User entered '30/Oct/2020 10:36'	System	30 Oct 2020 14:36:18

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:25:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:41:17
User entered '1'	(b) (4), (b) (6)	30 Oct 2020 14:36:18