

US3362244 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:59:56

All time stamps listed in this document are displayed in GMT

US3362244

Form: Participant Creation

Generated On: 26 Nov 2020 10:59:56

[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 10:59:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:56

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
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 10:59:56

Date of Informed Consent (<i>dd MMM yyyy</i>)	24 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:59:56

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:59:56

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:56

Condition	OSTEOPOROSIS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:56

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:56

Condition	FRACTURED PELVIS
Start date (dd MMM yyyy)	UN FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN APR 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	APR 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:56

Condition	OSTEOARTHRITIS BILATERAL HANDS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:56

Condition	POST MENOPAUSE
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:56

Condition	ALPHA THALASSEMIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:56

Condition	FRACTURED LEFT ELBOW
Start date (dd MMM yyyy)	UN FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN FEB 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	FEB 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:56

Condition	LEFT HIP PAIN
Start date (dd MMM yyyy)	UN FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
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 (9)

Generated On: 26 Nov 2020 10:59:56

Condition	DEGENERATIVE DISC DISEASE
Start date (dd MMM yyyy)	27 APR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:59:56

Condition	ABNORMAL HEART RHYTHM
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:54 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 13:54
Height (<i>xxx.x</i>)	164.2 cm
Weight (<i>xxx.x</i>)	55.7 kg
BMI (<i>xxx.x</i>)	20.65898 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:56

Date of assessment (*dd MMM yyyy*) 24 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown True

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

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Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	LIVES IN A BED AND BREAKFAST (b) (6)

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:56

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 187957

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 10:59:56

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	13:54 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 13:54
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 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 10:59:56

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	15:37 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 15:37
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 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 10:59:56

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) 24 AUG 2020

What was the treatment time? (00:00-23:59) 14:58 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 14:58

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 10:59:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	24 AUG 2020
Collection time (<i>00:00-23:59</i>)	14:32 (24 HR)
Collection date and time (derived)	24 AUG 2020 14:32

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:59:56

Collection date (<i>dd MMM yyyy</i>)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:12	24 AUG 2020 14:12
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

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 10:59:56

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 15:32

PC Open Date & Time

24 AUG 2020 15:18

PC Close Date & Time

24 AUG 2020 17:48

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 20:25

PC Open Date & Time

24 AUG 2020 18:43

PC Close Date & Time

25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:56

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	25 AUG 2020 12:37
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:59:56

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	26 AUG 2020 13:17
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:59:56

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	27 AUG 2020 12:27
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:59:56

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

96.4 °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

28 AUG 2020 12:09

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:59:56

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

97.7 °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

29 AUG 2020 12:17

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:59:56

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

96.8 °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

30 AUG 2020 12:23

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

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

24 AUG 2020 15:33

PC Open Date & Time

24 AUG 2020 15:18

PC Close Date & Time

24 AUG 2020 17:48

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

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

24 AUG 2020 20:26

PC Open Date & Time

24 AUG 2020 18:43

PC Close Date & Time

25 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:59:56

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

25 AUG 2020 12:38

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:59:56

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

26 AUG 2020 13:18

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:59:56

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

27 AUG 2020 12:28

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:59:56

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

28 AUG 2020 12:10

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:59:56

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

29 AUG 2020 12:17

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:59:56

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

30 AUG 2020 12:24

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 15:35
PC Open Date & Time	24 AUG 2020 15:18
PC Close Date & Time	24 AUG 2020 17:48

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 20:29
PC Open Date & Time	24 AUG 2020 18:43
PC Close Date & Time	25 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:56

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 ☒

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:56

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 12:39
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:56

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 ☒

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:56

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 13:19
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:56

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 ☒

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:56

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 12:29
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:56

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 ☒

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:56

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 12:10
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:56

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 ☒

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:56

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 12:18
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:56

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 ☒

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:56

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 12:24
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3362244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

Was Contact Attempted?

Yes ☒

No ☐

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

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362244

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

Was Contact Attempted?

Yes ☒

No ☐

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

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362244

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

Was Contact Attempted?

Yes ☒

No ☐

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

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362244

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	14:20 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 14:20
Temperature (xxx.x)	37.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

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

PATIENT DECLINED DUE TO ORTHOPEDIC SURGERY BEING NEEDED

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

Which arm was used to give treatment? Left Arm ☐
Right Arm ☐

What was the frequency of the study treatment dosing? _____

What was the route of administration for the study treatment? _____

US3362244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	23 SEP 2020
Collection time (<i>00:00-23:59</i>)	14:35 (24 HR)
Collection date and time (derived)	23 SEP 2020 14:35

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:59:56

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:42	23 SEP 2020 14:42
Nasopharyngeal Swab 2	No		

US3362244

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

Was Contact Attempted?

Yes ☒

No ☐

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

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362244

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

Was Contact Attempted?

Yes ☒

No ☐

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

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362244

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	28 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:38 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 12:38
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	90 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362244

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 OCT 2020

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

US3362244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	28 OCT 2020
Collection time (<i>00:00-23:59</i>)	12:50 (24 HR)
Collection date and time (derived)	28 OCT 2020 12:50

US3362244

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	26 OCT 2020 13:03:21
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 OCT 2020 09:19:18

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2020 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2020 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 MAY 2021 00:01
Patient Cloud Close Date & Time	16 MAY 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 JUN 2021 00:01
Patient Cloud Close Date & Time	06 JUN 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUN 2021 00:01
Patient Cloud Close Date & Time	27 JUN 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 JUL 2021 00:01
Patient Cloud Close Date & Time	11 JUL 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2021 00:01
Patient Cloud Close Date & Time	18 JUL 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2021 00:01
Patient Cloud Close Date & Time	29 AUG 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2021 00:01
Patient Cloud Close Date & Time	19 SEP 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2021 00:01
Patient Cloud Close Date & Time	24 OCT 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 NOV 2021 00:01
Patient Cloud Close Date & Time	14 NOV 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

DAY 502

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 JAN 2022 00:01
Patient Cloud Close Date & Time	16 JAN 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 FEB 2022 00:01
Patient Cloud Close Date & Time	20 FEB 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 FEB 2022 00:01
Patient Cloud Close Date & Time	27 FEB 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 MAR 2022 00:01
Patient Cloud Close Date & Time	20 MAR 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 APR 2022 00:01
Patient Cloud Close Date & Time	17 APR 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUN 2022 00:01
Patient Cloud Close Date & Time	19 JUN 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 JUL 2022 00:01
Patient Cloud Close Date & Time	10 JUL 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

DAY 698

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 JUL 2022 00:01
Patient Cloud Close Date & Time	24 JUL 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 AUG 2022 00:01
Patient Cloud Close Date & Time	14 AUG 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 SEP 2022 00:01
Patient Cloud Close Date & Time	25 SEP 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 OCT 2022 00:01
Patient Cloud Close Date & Time	23 OCT 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 OCT 2022 00:01
Patient Cloud Close Date & Time	30 OCT 2022 23:59

US3362244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

Was Contact Attempted?

Yes ☒

No ☐

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

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362244

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3362244

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:59:56

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3362244

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:59:56

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3362244

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:59:56

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

AEID

Adverse event

WORSENING OF LEFT HIP
PAIN/ARTHRITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

08 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)

11 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

v6.020 DTW (1102)

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US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

AEID	USA-US112-2020-MRNA-1273-P30 1000006
Adverse event	POST OPERATIVE INTRA-ABDOMINAL ABSCESS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	20 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

SUBJECT HAD A PLANNED
PROCEDURE FOR REPAIR OF
LEFT PUBIC RAMI DUE TO
CHRONIC/WORSENING
ARTHRITIS. PROCEDURE WENT
WELL INITIALLY, HOWEVER
ABSCESS DEVELOPED AND
REQUIRED INPATIENT
HOSPITALIZATION, SUBJECT
NOTIFIED STAFF ON 28OCT2020
REGARDING INPATIENT
TREATMENT

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

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

AEID	USA-US112-2020-MRNA-1273-P30 1000006
Adverse event	RIGHT AXILLARY DEEP VEIN THROMBOSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	19 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT HAD PICC LINE PLACED POST SURGERY, NOTE TO HAVE PAIN ON 10/19/2020 DIAGNOSED WITH DVT AND PICC LINE REMOVED, ON ANTI-COAGULANTS
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

v6.020 DTW (1102)

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US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

AEID	USA-US112-2020-MRNA-1273-P30 1000007
Adverse event	WORSENING OF ANTERIOR LEFT PELVIC RING NON-UNION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	09 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	05 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
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)	29 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	5 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

v6.020 DTW (1102)

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US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT HAD PLANNED PROCEDURE FOR REPAIR OF ANTERIOR LEFT PELVIC RING, DID NOT DISCLOSE HOSPITALIZATION.
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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

AEID	USA-US112-2020-MRNA-1273-P30 1000006
Adverse event	RIGHT BRACHIAL DEEP VEIN THROMBOSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	19 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT HAD PICC LINE PLACED POST SURGERY, NOTE TO HAVE PAIN ON 10/19/2020 DIAGNOSED WITH DVT AND PICC LINE REMOVED, ON ANTI-COAGULANTS
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)	

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

AEID	
Adverse event	DIARRHEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False
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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

AEID	
Adverse event	RASH
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False
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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:59:56

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

Yes ☒

No ☐

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

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

Name of Medication	ALENDRONATE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	OSTEOPOROSIS
Dose per administration	70
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input checked="" type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

Name of Medication	ATORVASTATIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERLIPIDEMIA
Dose per administration	80
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	3 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

Name of Medication	TYLENOL ARTHRITIS
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	OSTEOARTHRITIS
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input checked="" type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		UN UNK 2010
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

Name of Medication	TYLENOL EXTRA STRENGTH
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	OSTEOARTHRITIS
Dose per administration	325
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		25 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		27 AUG 2020
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

Name of Medication	TRAMADOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	ARTHRITIS
Dose per administration	25
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input checked="" type="checkbox"/>
If frequency is Other, specify	
Route of administration	EVERY 12 HOURS Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		UN FEB 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

Name of Medication	HYDROCODONE/ACETAMINOP HEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PAIN SECONDARY WORSENING OF ANTERIOR LEFT PELVIC RING NON-UNION
Dose per administration	7.5/325
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input checked="" type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

Name of Medication	METHYLPREDNISOLONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PAIN/ HIP FRACTURE
Dose per administration	4
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	DOSE PACK
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		9 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		13 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

Name of Medication	GABAPENTIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	WORSENING OF ANTERIOR LEFT PELVIC RING NON-UNION
Dose per administration	100
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input checked="" type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 3 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

Name of Medication	DULCOLAX
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HELP PREVENT CONSTIPATION FROM PAIN MEDICATION
Dose per administration	1
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 29 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

Name of Medication	APIXABAN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	RIGHT AXILLARY AND BRACHIAL DEEP VEIN THROMBOSIS
Dose per administration	5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

Name of Medication	DICLOFENAC EC
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LEFT HIP PAIN DUE TO WORSENING OF ANTERIOR LEFT PELVIC RING NON-UNION
Dose per administration	50
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

Name of Medication	RIFAMPIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	POST OPERATIVE INTRA-ABDOMINAL ABSCESS
Dose per administration	300
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 3 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

Name of Medication	ANCEF
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	POST OPERATIVE INTRA-ABDOMINAL ABSCESS
Dose per administration	2
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input checked="" type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input checked="" type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		3 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

Name of Medication	FERROUS SULFATE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	ALPHA THALASSEMIA
Dose per administration	324
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (<i>dd MMM yyyy</i>)		20 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

Name of Medication	LACTATED RINGERS
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	IV HYDRATION SECONDARY TO POST OPERATIVE INTRA-ABDOMINAL ABSCESS
Dose per administration	1000
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

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

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

Name of Medication	LINEZOLID
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	POST-OPERATIVE INTRABDOMINAL ABSCESS
Dose per administration	600
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input checked="" type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		4 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 13 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

Name of Medication	DAPTOMYCIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	POST OPERATIVE INTRABDOMINAL ABSCESS
Dose per administration	420
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		9 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

Name of Medication	CALCIUM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	OSTEOPOROSIS
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

Name of Medication	PROLIA
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	OSTEOPOROSIS
Dose per administration	60
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	
Route of administration	EVERY 6 MONTHS Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:59:56

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:59:56

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
13 OCT 2020	DRAINAGE OF ABSCESS	Adverse Event	
29 SEP 2020	LEFT PELVIC RING FRACTURE NONUNION REPAIR	Adverse Event	

US3362244

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:59:56

Date of dosing discontinuation (dd MMM yyyy)

23 SEP 2020

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

AE ID 1

US3362244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:59:56

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 ☐

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

SAEID	USA-US112-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:59:56

SAEID	USA-US112-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	29/OCT/2020 18:59
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.	True

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:59:56

SAEID	USA-US112-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	30/OCT/2020 13:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	False

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:59:56

SAEID	USA-US112-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/NOV/2020 10:04
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:59:56

SAEID	USA-US112-2020-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	11/NOV/2020 19:08
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

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

SAEID	USA-US112-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:59:56

SAEID	USA-US112-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/NOV/2020 10:04
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:59:56

SAEID	USA-US112-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	10/NOV/2020 11:32
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

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:59:56

SAEID	USA-US112-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	11/NOV/2020 20:31
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

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:59:56

SAEID	USA-US112-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	13/NOV/2020 13:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 10:59:56

SAEID	USA-US112-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/NOV/2020 19:28
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

US3362244 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

US3362244

Form: Participant Creation

Generated On: 26 Nov 2020 10:59:56

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3362244'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	24 Aug 2020 18:39:16

US3362244

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:59:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 20:13:55

US3362244

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Aug 2020 18:39:17

US3362244

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Aug 2020 20:13:55

US3362244

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:59:56

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	24 Aug 2020 20:13:55

US3362244

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:56

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1954'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Aug 2020 18:39:19

US3362244

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:56

[Age](#)

Audit	User	Time (GMT)
User entered '66'	(b) (4), (b) (6)	24 Aug 2020 20:14:16

US3362244

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:56

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	24 Aug 2020 20:14:16

US3362244

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:56

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '66'	System	24 Aug 2020 20:14:37

US3362244

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:56

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	24 Aug 2020 20:14:16

US3362244

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:56

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	24 Aug 2020 20:14:16

US3362244

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:56

[White](#)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	24 Aug 2020 20:14:16

US3362244

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:56

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 20:14:16

US3362244

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:56

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 20:14:16

US3362244

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:56

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 20:14:16

US3362244

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:56

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 20:14:16

US3362244

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:56

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 20:14:16

US3362244

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:56

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 20:14:16

US3362244

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:56

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 20:14:16

US3362244

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:59:56

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 20:14:16

US3362244

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:56

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 20:14:37

US3362244

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	24 Aug 2020 20:14:37

US3362244

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '2020'	System	24 Aug 2020 20:14:37

US3362244

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:56

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	24 Aug 2020 20:14:37

US3362244

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 20:14:37

US3362244

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 20:14:37

US3362244

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:56

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 20:14:37

US3362244

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:56

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 20:14:37

US3362244

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:56

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Aug 2020 18:39:17

US3362244

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:59:56

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Aug 2020 20:14:41

US3362244

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 20:14:41

US3362244

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:59:56

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 14:49:17

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:56

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:51:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:51:33
Data point term sent to Coder	System	25 Aug 2020 14:50:20
User entered 'Osteoporosis'	(b) (4), (b) (6) (b) (4)	25 Aug 2020 14:50:01

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	(b) (4), (b) (6)	25 Aug 2020 14:50:01

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 14:50:01

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 14:50:01

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:50:01

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 14:50:01

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	25 Aug 2020 14:50:01

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '2010'	System	25 Aug 2020 14:50:01

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 14:50:01

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 14:50:01

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:56

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:52:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:52:39
Data point term sent to Coder	System	25 Aug 2020 14:51:20
User entered 'Hyperlipidemia'	(b) (4), (b) (6) (b) (4)	25 Aug 2020 14:50:23

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	25 Aug 2020 14:50:23

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 14:50:23

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 14:50:23

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:50:23

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 14:50:23

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	25 Aug 2020 14:50:23

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '2015'	System	25 Aug 2020 14:50:23

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 14:50:23

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 14:50:23

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:56

Condition

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. This condition typically should have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' canceled (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 04:31:52
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. This condition typically should have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 04:31:24
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Pelvic fractures and dislocations, PT: Pelvic fracture, LLT: Fracture of pelvis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:52:39
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 14:52:39
Data point term sent to Coder	System	25 Aug 2020 14:51:20
User entered 'Fractured pelvis'	(b) (4), (b) (6)	25 Aug 2020 14:50:48

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. This condition typically should have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:07:46
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. This condition typically should have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' answered with 'condition is not ongoing ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:36:26
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. This condition typically should have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 04:32:07
User entered 'un Feb 2020'	(b) (4), (b) (6)	25 Aug 2020 14:50:48

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 14:50:48

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 14:50:48

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User closed query 'Per CDM CR: Please review the stop date of this MH as the duration is unexpected for this medical condition. The effects of FRACTURED PELVIS may be ongoing or with a longer duration but the event itself is not. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 18:32:32
Query 'Per CDM CR: Please review the stop date of this MH as the duration is unexpected for this medical condition. The effects of FRACTURED PELVIS may be ongoing or with a longer duration but the event itself is not. Please correct dates or provide explanation for the Med History duration. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 20:40:36
User entered 'UN Apr 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 20:40:25
User entered 'UN Feb 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 21:41:26
User opened query 'Per CDM CR: Please review the stop date of this MH as the duration is unexpected for this medical condition. The effects of FRACTURED PELVIS may be ongoing or with a longer duration but the event itself is not. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 17:06:42
User entered 'un Apr 2020'	(b) (4), (b) (6)	25 Aug 2020 14:50:48

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 14:50:48

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Feb 2020'	System	25 Aug 2020 14:50:48

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '2020'	System	25 Aug 2020 14:50:48

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Apr 2020'	System	26 Oct 2020 20:40:25
User entered 'Feb 2020'	System	22 Oct 2020 21:41:26
User entered 'Apr 2020'	System	25 Aug 2020 14:50:48

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '2020'	System	25 Aug 2020 14:50:48

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:56

Condition

Audit	User	Time (GMT)
User closed query 'Per CDM (DM CLR RQ): Site response noted. Please ensure the location of osteoarthritis is recorded in the eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 12:09:48
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hand osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	03 Nov 2020 17:07:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Nov 2020 17:07:22
Data point term sent to Coder	System	03 Nov 2020 17:06:27
Query 'Per CDM (DM CLR RQ): Site response noted. Please ensure the location of osteoarthritis is recorded in the eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 17:06:16
Coding entries removed.	(b) (4), (b) (6)	03 Nov 2020 17:06:12
User entered 'OSTEOARTHRITIS Bilateral hands' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 17:06:12
User opened query 'Per CDM (DM CLR RQ): Site response noted. Please ensure the location of osteoarthritis is recorded in the eCRF. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 15:50:37
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid, Osteoarthritis, etc.) and the location. 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)	03 Nov 2020 15:50:37
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 16:36:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 16:36:55

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:56

Condition

Audit	User	Time (GMT)
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid, Osteoarthritis, etc.) and the location. 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 'updated' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:36:27
Data point term sent to Coder	System	30 Oct 2020 16:36:21
Coding entries removed.	(b) (4), (b) (6)	30 Oct 2020 16:36:20
User entered 'OSTEOARTHRITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:36:20
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid, Osteoarthritis, etc.) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.'	(b) (4), (b) (6)	26 Oct 2020 10:34:56
(Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 21:40:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 21:40:45
Data point term sent to Coder	System	03 Sep 2020 21:39:58
User entered 'ARTHRITIS'	Crystal Rowell (b) (4)	03 Sep 2020 21:39:23

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	03 Sep 2020 21:39:35
User entered 'UN UNK 2020'	Crystal Rowell (b) (4) (b) (4)	03 Sep 2020 21:39:23

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Crystal Rowell (b) (4) (b) (4)	03 Sep 2020 21:39:23

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	03 Sep 2020 21:39:23

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	03 Sep 2020 21:39:23

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Crystal Rowell (b) (4) (b) (4)	03 Sep 2020 21:39:23

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	03 Sep 2020 21:39:35
User entered 'Jan 2020'	System	03 Sep 2020 21:39:23

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '2010'	System	03 Sep 2020 21:39:35
User entered '2020'	System	03 Sep 2020 21:39:23

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:39:23

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 21:39:23

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:56

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:07:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:07:40
Data point term sent to Coder	System	17 Sep 2020 18:06:52
User entered 'post menopause'	(b) (4), (b) (6) (b) (4)	17 Sep 2020 18:05:57

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 18:05:57

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	17 Sep 2020 18:05:57

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 18:05:57

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 18:05:57

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 18:05:57

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 18:05:57

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 18:05:57

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 18:05:57

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 18:05:57

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:56

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Blood and lymphatic system disorders congenital, HLT: Haemoglobinopathies congenital, PT: Thalassaemia alpha, LLT: Thalassaemia alpha - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 19:31:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 19:31:56
Data point term sent to Coder	System	30 Oct 2020 19:31:19
User entered 'Alpha Thalassemia'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:30:19

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:30:19

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered 'I'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:30:19

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:30:19

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:30:19

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:30:19

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 19:30:19

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 19:30:19

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 19:30:19

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 19:30:19

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:56

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Upper limb fracture, LLT: Elbow fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 21:11:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 21:11:34
Data point term sent to Coder	System	12 Nov 2020 21:10:27
User entered 'Fractured left elbow'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:09:43

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'un Feb 2020'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:09:43

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:09:43

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:09:43

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'un Feb 2020'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:09:43

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:09:43

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Feb 2020'	System	12 Nov 2020 21:09:43

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '2020'	System	12 Nov 2020 21:09:43

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Feb 2020'	System	12 Nov 2020 21:09:43

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '2020'	System	12 Nov 2020 21:09:43

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:56

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 21:15:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 21:15:34
Data point term sent to Coder	System	12 Nov 2020 21:14:33
User entered 'left hip pain'	Crystal Rowell (b) (4)	12 Nov 2020 21:14:32
	(b) (4)	

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'un Feb 2020'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:14:32

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:14:32

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:14:32

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:14:32

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:14:32

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Feb 2020'	System	12 Nov 2020 21:14:32

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '2020'	System	12 Nov 2020 21:14:32

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:14:32

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:14:32

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:56

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 21:31:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 21:31:34
Data point term sent to Coder	System	12 Nov 2020 21:15:34
User entered 'degenerative disc disease'	Crystal Rowell (b) (4)	12 Nov 2020 21:15:21

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '27 Apr 2020'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:15:21

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:15:21

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:15:21

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:15:21

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:15:21

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Apr 2020'	System	12 Nov 2020 21:15:21

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '2020'	System	12 Nov 2020 21:15:21

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:15:21

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:15:21

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:59:56

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Arrhythmia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:39:44
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:39:44
Data point term sent to Coder	System	12 Nov 2020 21:16:35
User entered 'abnormal heart rhythm'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:15:50

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:15:50

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered 'I'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:15:50

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:59:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:15:50

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:15:50

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:59:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 21:15:50

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:15:50

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:15:50

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:15:50

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:15:50

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 14:57:22

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 14:57:22

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '13:54'	(b) (4), (b) (6)	25 Aug 2020 14:57:22

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 13:54'	System	25 Aug 2020 14:57:22

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '164.2' cm	(b) (4), (b) (6)	25 Aug 2020 14:57:22
DataPoint set to visible.	System	24 Aug 2020 20:14:41

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '55.7' kg	(b) (4), (b) (6)	25 Aug 2020 14:57:22
DataPoint set to visible.	System	24 Aug 2020 20:14:41

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '20.65898'	System	17 Sep 2020 00:21:42
User entered '20.7'	System	25 Aug 2020 14:57:22
DataPoint set to visible.	System	24 Aug 2020 20:14:41

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	25 Aug 2020 14:57:22
DataPoint set to visible.	System	24 Aug 2020 20:14:41

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. For Visit 1 Day 1 Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:32:52
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. For Visit 1 Day 1 Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' answered with 'Data updated per query resolution.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 14:58:18
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	22 Sep 2020 14:58:11
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. For Visit 1 Day 1 Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 13:50:40
User entered '36.6' C	(b) (4), (b) (6)	25 Aug 2020 14:57:22

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	22 Sep 2020 14:58:11
User entered 'Oral (Oral)'	(b) (4), (b) (6)	25 Aug 2020 14:57:22

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:57:22

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	22 Sep 2020 14:58:11
User entered '70'	(b) (4), (b) (6)	25 Aug 2020 14:57:22

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Aug 2020 14:57:22

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	22 Sep 2020 14:58:11
User entered '18'	(b) (4), (b) (6)	25 Aug 2020 14:57:22

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Aug 2020 14:57:22

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	22 Sep 2020 14:58:11
User entered '158'	(b) (4), (b) (6)	25 Aug 2020 14:57:22

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 14:57:22

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	22 Sep 2020 14:58:11
User entered '95'	(b) (4), (b) (6)	25 Aug 2020 14:57:22

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 14:57:22

US3362244

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 14:57:45

US3362244

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:56

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 14:57:45

US3362244

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 15:03:46

US3362244

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:56

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:03:46

US3362244

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:56

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 06:32:48
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'post menopause is entered in ecrf' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 18:06:12
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 09:18:44
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	25 Aug 2020 15:03:46

US3362244

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:56

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:03:46

US3362244

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:03:46

US3362244

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:56

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:03:46

US3362244

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:03:46

US3362244

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 10:59:56

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	25 Aug 2020 15:03:46

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

Other

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:59:56

[Specify](#)

Audit	User	Time (GMT)
User entered 'Lives in a bed and breakfast (b) (6) (b) (6)	(b) (4), (b) (6)	25 Aug 2020 15:04:34

US3362244

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:04:50

US3362244

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 15:04:50

US3362244

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Aug 2020 15:04:50

US3362244

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:59:56

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	25 Aug 2020 15:04:50

US3362244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	24 Aug 2020 19:40:17

US3362244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:56

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '187957'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	24 Aug 2020 19:40:17

US3362244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	24 Aug 2020 19:40:17

US3362244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:05:09

US3362244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:05:09

US3362244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:05:09

US3362244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:56

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:05:09

US3362244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:56

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:05:09

US3362244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Thomassie (b) (4)	24 Sep 2020 00:12:50
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:40:19
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:43:10

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:56

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 05:21:02
Query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:11:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Sep 2020 13:11:22
User opened query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:33:24
User entered '164.2' cm	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:56

[Weight](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Sep 2020 13:11:22
User entered '55.7' kg	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:56

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 05:21:02
Query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:11:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Sep 2020 13:11:22
User opened query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:33:24
User entered '164.2' cm	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:56

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Sep 2020 13:11:22
User entered '55.7' kg	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '13:54'	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 13:54'	System	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

Pulse (xxx)

Audit	User	Time (GMT)
User entered '70'	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 20:47:13
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS; runs normal at home and at last check up' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 15:09:34
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	25 Aug 2020 15:07:23
User entered '158'	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '95'	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:56

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 05:21:02
Query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:11:26
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Sep 2020 13:11:22
User opened query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:33:24
User entered '164.2' cm	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:59:56

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	23 Sep 2020 13:11:22
User entered '55.7' kg	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '15:37'	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 15:37'	System	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '62'	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '130'	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '81'	(b) (4), (b) (6)	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	25 Aug 2020 15:07:23

US3362244

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:56

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:09:59

US3362244

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:56

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 15:09:59

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 20:15:12

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 20:15:12

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 20:15:12

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 20:15:12

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

What was the treatment date? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 20:15:12

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '14:58'	(b) (4), (b) (6)	24 Aug 2020 20:15:12

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 14:58'	System	24 Aug 2020 20:15:12

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	24 Aug 2020 20:15:12

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	24 Aug 2020 20:15:12

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 20:15:12

US3362244

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:10:37

US3362244

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 15:10:37

US3362244

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:32'	(b) (4), (b) (6)	25 Aug 2020 15:10:37

US3362244

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 14:32'	System	25 Aug 2020 15:10:37

US3362244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:59:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 15:11:02

US3362244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:56

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	25 Aug 2020 15:11:02

US3362244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:11:02

US3362244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '14:12'	(b) (4), (b) (6)	25 Aug 2020 15:11:02

US3362244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 14:12'	System	25 Aug 2020 15:11:02

US3362244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:56

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	25 Aug 2020 15:11:02

US3362244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:11:02

US3362244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:11:02

US3362244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 15:11:02

US3362244

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:13:55

US3362244

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:13:55

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-24T15:32:03', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'af9118eb-1a39-4274-a7fc-4121a3a73e96'	System	24 Aug 2020 20:32:42
User entered 'Yes (Y)'	System	24 Aug 2020 20:32:42

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:32:14', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'af9118eb-1a39-4274-a7fc-4121a3a73e96'	System	24 Aug 2020 20:32:42
User entered '98.3'	System	24 Aug 2020 20:32:42

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:32:26', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'af9118eb-1a39-4274-a7fc-4121a3a73e96'	System	24 Aug 2020 20:32:42
User entered 'No (N)'	System	24 Aug 2020 20:32:42

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:32:36', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'af9118eb-1a39-4274-a7fc-4121a3a73e96'	System	24 Aug 2020 20:32:42
User entered '24 Aug 2020 15:32'	System	24 Aug 2020 20:32:42

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 15:18'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 17:48'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:24:41', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2b041188-345a-4672-af37-19e64258b737'	System	25 Aug 2020 01:25:14
User entered 'Yes (Y)'	System	25 Aug 2020 01:25:14

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:24:52', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2b041188-345a-4672-af37-19e64258b737'	System	25 Aug 2020 01:25:14
User entered '97.3'	System	25 Aug 2020 01:25:14

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:24:59', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2b041188-345a-4672-af37-19e64258b737'	System	25 Aug 2020 01:25:14
User entered 'No (N)'	System	25 Aug 2020 01:25:14

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:25:09', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2b041188-345a-4672-af37-19e64258b737'	System	25 Aug 2020 01:25:14
User entered '24 Aug 2020 20:25'	System	25 Aug 2020 01:25:14

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 18:43'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 2'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:56

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:36:40', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ae723385-7d29-4c4f-aa8c-8e17f95b0d35'	System	25 Aug 2020 17:37:15
User entered 'Yes (Y)'	System	25 Aug 2020 17:37:15

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:56

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-25T12:36:46', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ae723385-7d29-4c4f-aa8c-8e17f95b0d35'	System	25 Aug 2020 17:37:15
User entered '97.3'	System	25 Aug 2020 17:37:15

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-25T12:36:51', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ae723385-7d29-4c4f-aa8c-8e17f95b0d35'	System	25 Aug 2020 17:37:15
User entered 'Yes (Y)'	System	25 Aug 2020 17:37:15

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-25T12:37:02', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ae723385-7d29-4c4f-aa8c-8e17f95b0d35'	System	25 Aug 2020 17:37:15
User entered '0'	System	25 Aug 2020 17:37:15

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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).	(b) (4), (b) (6)	07 Sep 2020 10:50:16
Query 'Per the participant response, medication was taken to prevent 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 'con med list updated ' (Site from System).	Crystal Rowell (b) (4)	31 Aug 2020 23:47:22
User opened query 'Per the participant response, medication was taken to prevent 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).	System	25 Aug 2020 17:37:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-25T12:37:02', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ae723385-7d29-4c4f-aa8c-8e17f95b0d35'	System	25 Aug 2020 17:37:15
User entered '1'	System	25 Aug 2020 17:37:15

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:37:10', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ae723385-7d29-4c4f-aa8c-8e17f95b0d35'	System	25 Aug 2020 17:37:15
User entered '25 Aug 2020 12:37'	System	25 Aug 2020 17:37:15

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 3'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:59:56

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-26T13:17:05', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2f2ee995-d331-4167-ac90-dc23ea577fd0'	System	26 Aug 2020 18:17:47
User entered 'Yes (Y)'	System	26 Aug 2020 18:17:47

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:59:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-26T13:17:19', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2f2ee995-d331-4167-ac90-dc23ea577fd0'	System	26 Aug 2020 18:17:47
User entered '96.7'	System	26 Aug 2020 18:17:47

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:17:23', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2f2ee995-d331-4167-ac90-dc23ea577fd0'	System	26 Aug 2020 18:17:47
User entered 'Yes (Y)'	System	26 Aug 2020 18:17:47

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:17:30', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2f2ee995-d331-4167-ac90-dc23ea577fd0'	System	26 Aug 2020 18:17:47
User entered '0'	System	26 Aug 2020 18:17:47

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:59:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Participant was contacted. Subject took Tylenol Extra Strength 325mg for arthritis. Con med log will be updated' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 06:17:00
User opened query 'Per the participant response, medication was taken to prevent 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).	System	26 Aug 2020 18:17:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:17:30', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2f2ee995-d331-4167-ac90-dc23ea577fd0'	System	26 Aug 2020 18:17:47
User entered '1'	System	26 Aug 2020 18:17:47

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:59:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-26T13:17:44', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2f2ee995-d331-4167-ac90-dc23ea577fd0'	System	26 Aug 2020 18:17:47
User entered '26 Aug 2020 13:17'	System	26 Aug 2020 18:17:47

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 4'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:59:56

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:27:09', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8e918026-3fbb-43db-862e-8e2869476e02'	System	27 Aug 2020 17:27:37
User entered 'Yes (Y)'	System	27 Aug 2020 17:27:37

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:59:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-27T12:27:18', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8e918026-3fbb-43db-862e-8e2869476e02'	System	27 Aug 2020 17:27:37
User entered '97.3'	System	27 Aug 2020 17:27:37

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-27T12:27:23', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8e918026-3fbb-43db-862e-8e2869476e02'	System	27 Aug 2020 17:27:37
User entered 'Yes (Y)'	System	27 Aug 2020 17:27:37

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:27:26', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8e918026-3fbb-43db-862e-8e2869476e02'	System	27 Aug 2020 17:27:37
User entered '0'	System	27 Aug 2020 17:27:37

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:59:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Participant was contacted. Subject took Tylenol Extra Strength 325mg for arthritis. Con med log will be updated' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 06:16:56
User opened query 'Per the participant response, medication was taken to prevent 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).	System	27 Aug 2020 17:27:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:27:26', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8e918026-3fbb-43db-862e-8e2869476e02'	System	27 Aug 2020 17:27:37
User entered '1'	System	27 Aug 2020 17:27:37

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:59:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:27:34', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8e918026-3fbb-43db-862e-8e2869476e02'	System	27 Aug 2020 17:27:37
User entered '27 Aug 2020 12:27'	System	27 Aug 2020 17:27:37

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 5'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:59:56

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-28T12:09:22', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cc1a01bc-7a22-414c-9432-1552900724b9'	System	28 Aug 2020 17:09:48
User entered 'Yes (Y)'	System	28 Aug 2020 17:09:48

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:59:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-28T12:09:29', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cc1a01bc-7a22-414c-9432-1552900724b9'	System	28 Aug 2020 17:09:48
User entered '96.4'	System	28 Aug 2020 17:09:48

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:09:33', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cc1a01bc-7a22-414c-9432-1552900724b9'	System	28 Aug 2020 17:09:48
User entered 'No (N)'	System	28 Aug 2020 17:09:48

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:59:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-28T12:09:41', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cc1a01bc-7a22-414c-9432-1552900724b9'	System	28 Aug 2020 17:09:48
User entered '28 Aug 2020 12:09'	System	28 Aug 2020 17:09:48

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 6'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:59:56

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:16:55', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c3f62e15-855c-46fc-a04b-4c8cb896b0d7'	System	29 Aug 2020 17:17:26
User entered 'Yes (Y)'	System	29 Aug 2020 17:17:26

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:59:56

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-29T12:17:07', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c3f62e15-855c-46fc-a04b-4c8cb896b0d7'	System	29 Aug 2020 17:17:26
User entered '97.7'	System	29 Aug 2020 17:17:26

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:17:18', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c3f62e15-855c-46fc-a04b-4c8cb896b0d7'	System	29 Aug 2020 17:17:26
User entered 'No (N)'	System	29 Aug 2020 17:17:26

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:59:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:17:23', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c3f62e15-855c-46fc-a04b-4c8cb896b0d7'	System	29 Aug 2020 17:17:26
User entered '29 Aug 2020 12:17'	System	29 Aug 2020 17:17:26

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 7'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:59:56

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-30T12:23:15', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '88bac18d-2495-4b6d-85b6-d51c611aa234'	System	30 Aug 2020 17:23:42
User entered 'Yes (Y)'	System	30 Aug 2020 17:23:42

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:59:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:23:26', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '88bac18d-2495-4b6d-85b6-d51c611aa234'	System	30 Aug 2020 17:23:42
User entered '96.8'	System	30 Aug 2020 17:23:42

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-30T12:23:31', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '88bac18d-2495-4b6d-85b6-d51c611aa234'	System	30 Aug 2020 17:23:42
User entered 'No (N)'	System	30 Aug 2020 17:23:42

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:59:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-30T12:23:37', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '88bac18d-2495-4b6d-85b6-d51c611aa234'	System	30 Aug 2020 17:23:42
User entered '30 Aug 2020 12:23'	System	30 Aug 2020 17:23:42

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

[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 (82cbad1a1791eaaaf)', Time: '2020-08-24T15:33:04', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '07c4e584-095f-4af3-ba05-e3567c2144cc'	System	24 Aug 2020 20:33:49
User entered 'None (1)'	System	24 Aug 2020 20:33:49

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-24T15:33:09', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '07c4e584-095f-4af3-ba05-e3567c2144cc'	System	24 Aug 2020 20:33:49
User entered 'No (N)'	System	24 Aug 2020 20:33:49

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-24T15:33:14', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '07c4e584-095f-4af3-ba05-e3567c2144cc'	System	24 Aug 2020 20:33:49
User entered 'No (N)'	System	24 Aug 2020 20:33:49

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

[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 (82cbad1a1791eaaf)', Time: '2020-08-24T15:33:28', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '07c4e584-095f-4af3-ba05-e3567c2144cc'	System	24 Aug 2020 20:33:49
User entered 'None (1)'	System	24 Aug 2020 20:33:49

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-24T15:33:45', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '07c4e584-095f-4af3-ba05-e3567c2144cc'	System	24 Aug 2020 20:33:49
User entered '24 Aug 2020 15:33'	System	24 Aug 2020 20:33:49

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 15:18'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 17:48'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

[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 (82cbad1a1791eaaf)', Time: '2020-08-24T20:26:06', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1375d2d8-e97e-4ce2-9985-105b615d02fe'	System	25 Aug 2020 01:26:36
User entered 'None (1)'	System	25 Aug 2020 01:26:36

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:26:10', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1375d2d8-e97e-4ce2-9985-105b615d02fe'	System	25 Aug 2020 01:26:36
User entered 'No (N)'	System	25 Aug 2020 01:26:36

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:26:14', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1375d2d8-e97e-4ce2-9985-105b615d02fe'	System	25 Aug 2020 01:26:36
User entered 'No (N)'	System	25 Aug 2020 01:26:36

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

[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 (82cbad1a1791eaaf)', Time: '2020-08-24T20:26:22', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1375d2d8-e97e-4ce2-9985-105b615d02fe'	System	25 Aug 2020 01:26:36
User entered 'None (1)'	System	25 Aug 2020 01:26:36

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-24T20:26:32', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1375d2d8-e97e-4ce2-9985-105b615d02fe'	System	25 Aug 2020 01:26:36
User entered '24 Aug 2020 20:26'	System	25 Aug 2020 01:26:36

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 18:43'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 2'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:59:56

[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 (82cbad1a1791eaaaf)', Time: '2020-08-25T12:37:40', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8d0a8083-f30a-4e51-9e70-eb811b38bd81'	System	25 Aug 2020 17:38:08
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 17:38:08

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-25T12:37:44', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8d0a8083-f30a-4e51-9e70-eb811b38bd81'	System	25 Aug 2020 17:38:08
User entered 'No (N)'	System	25 Aug 2020 17:38:08

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-25T12:37:47', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8d0a8083-f30a-4e51-9e70-eb811b38bd81'	System	25 Aug 2020 17:38:08
User entered 'No (N)'	System	25 Aug 2020 17:38:08

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:59:56

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 (82cbad1a1791eaaf)', Time: '2020-08-25T12:37:54', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8d0a8083-f30a-4e51-9e70-eb811b38bd81'	System	25 Aug 2020 17:38:08
User entered 'None (1)'	System	25 Aug 2020 17:38:08

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:59:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-25T12:38:04', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8d0a8083-f30a-4e51-9e70-eb811b38bd81'	System	25 Aug 2020 17:38:08
User entered '25 Aug 2020 12:38'	System	25 Aug 2020 17:38:08

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 3'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:59:56

[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 (82cbad1a1791eaf)', Time: '2020-08-26T13:18:01', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '79a284ee-76b8-4776-8001-46593ebbb64f'	System	26 Aug 2020 18:18:35
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 18:18:35

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-26T13:18:07', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '79a284ee-76b8-4776-8001-46593ebbb64f'	System	26 Aug 2020 18:18:35
User entered 'No (N)'	System	26 Aug 2020 18:18:35

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:18:12', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '79a284ee-76b8-4776-8001-46593ebbb64f'	System	26 Aug 2020 18:18:35
User entered 'No (N)'	System	26 Aug 2020 18:18:35

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:59:56

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 (82cbad1a1791eaaf)', Time: '2020-08-26T13:18:15', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '79a284ee-76b8-4776-8001-46593ebbb64f'	System	26 Aug 2020 18:18:35
User entered 'None (1)'	System	26 Aug 2020 18:18:35

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:59:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:18:29', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '79a284ee-76b8-4776-8001-46593ebbb64f'	System	26 Aug 2020 18:18:35
User entered '26 Aug 2020 13:18'	System	26 Aug 2020 18:18:35

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 4'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:59:56

[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 (82cbad1a1791eaaf)', Time: '2020-08-27T12:28:14', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '256865c5-82f8-4f2d-8ef9-f67b417429b5'	System	27 Aug 2020 17:28:38
User entered 'None (1)'	System	27 Aug 2020 17:28:38

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:59:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:28:18', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '256865c5-82f8-4f2d-8ef9-f67b417429b5'	System	27 Aug 2020 17:28:38
User entered 'No (N)'	System	27 Aug 2020 17:28:38

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-27T12:28:21', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '256865c5-82f8-4f2d-8ef9-f67b417429b5'	System	27 Aug 2020 17:28:38
User entered 'No (N)'	System	27 Aug 2020 17:28:38

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:59:56

[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 (82cbad1a1791eaaf)', Time: '2020-08-27T12:28:25', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '256865c5-82f8-4f2d-8ef9-f67b417429b5'	System	27 Aug 2020 17:28:38
User entered 'None (1)'	System	27 Aug 2020 17:28:38

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:59:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-27T12:28:33', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '256865c5-82f8-4f2d-8ef9-f67b417429b5'	System	27 Aug 2020 17:28:38
User entered '27 Aug 2020 12:28'	System	27 Aug 2020 17:28:38

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 5'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:59:56

[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 (82cbad1a1791eaaf)', Time: '2020-08-28T12:09:51', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ec06e05b-9122-46d4-840e-33e0923eb55d'	System	28 Aug 2020 17:10:15
User entered 'None (1)'	System	28 Aug 2020 17:10:15

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:59:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:09:54', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ec06e05b-9122-46d4-840e-33e0923eb55d'	System	28 Aug 2020 17:10:15
User entered 'No (N)'	System	28 Aug 2020 17:10:15

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-28T12:09:57', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ec06e05b-9122-46d4-840e-33e0923eb55d'	System	28 Aug 2020 17:10:15
User entered 'No (N)'	System	28 Aug 2020 17:10:15

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:59:56

[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 (82cbad1a1791eaaf)', Time: '2020-08-28T12:10:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ec06e05b-9122-46d4-840e-33e0923eb55d'	System	28 Aug 2020 17:10:15
User entered 'None (1)'	System	28 Aug 2020 17:10:15

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:59:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-28T12:10:11', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ec06e05b-9122-46d4-840e-33e0923eb55d'	System	28 Aug 2020 17:10:15
User entered '28 Aug 2020 12:10'	System	28 Aug 2020 17:10:15

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 6'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:59:56

[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 (82cbad1a1791eaaf)', Time: '2020-08-29T12:17:32', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ffee91b8-a86f-4f09-adaf-466a5683e0fc'	System	29 Aug 2020 17:17:55
User entered 'None (1)'	System	29 Aug 2020 17:17:55

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-29T12:17:35', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ffee91b8-a86f-4f09-adaf-466a5683e0fc'	System	29 Aug 2020 17:17:55
User entered 'No (N)'	System	29 Aug 2020 17:17:55

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:17:38', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ffee91b8-a86f-4f09-adaf-466a5683e0fc'	System	29 Aug 2020 17:17:55
User entered 'No (N)'	System	29 Aug 2020 17:17:55

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:59:56

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 (82cbad1a1791eaaf)', Time: '2020-08-29T12:17:42', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ffee91b8-a86f-4f09-adaf-466a5683e0fc'	System	29 Aug 2020 17:17:55
User entered 'None (1)'	System	29 Aug 2020 17:17:55

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:59:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-29T12:17:50', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ffee91b8-a86f-4f09-adaf-466a5683e0fc'	System	29 Aug 2020 17:17:55
User entered '29 Aug 2020 12:17'	System	29 Aug 2020 17:17:55

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 7'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:59:56

[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 (82cbad1a1791eaaaf)', Time: '2020-08-30T12:23:43', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cce5ffe-4e40-4359-a663-da90ab1bed81'	System	30 Aug 2020 17:24:06
User entered 'None (1)'	System	30 Aug 2020 17:24:06

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-30T12:23:48', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cce5ffe-4e40-4359-a663-da90ab1bed81'	System	30 Aug 2020 17:24:06
User entered 'No (N)'	System	30 Aug 2020 17:24:06

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:23:51', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cce5ffe-4e40-4359-a663-da90ab1bed81'	System	30 Aug 2020 17:24:06
User entered 'No (N)'	System	30 Aug 2020 17:24:06

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:59:56

[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 (82cbad1a1791eaaaf)', Time: '2020-08-30T12:23:54', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cce5ffe-4e40-4359-a663-da90ab1bed81'	System	30 Aug 2020 17:24:06
User entered 'None (1)'	System	30 Aug 2020 17:24:06

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:59:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-30T12:24:02', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cce5ffe-4e40-4359-a663-da90ab1bed81'	System	30 Aug 2020 17:24:06
User entered '30 Aug 2020 12:24'	System	30 Aug 2020 17:24:06

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:35:03', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '27d148b1-c036-469c-b82a-25bed34c24e7'	System	24 Aug 2020 20:35:56
User entered 'No interference with activity (1)'	System	24 Aug 2020 20:35:56

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-24T15:35:11', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '27d148b1-c036-469c-b82a-25bed34c24e7'	System	24 Aug 2020 20:35:56
User entered 'No interference with activity (1)'	System	24 Aug 2020 20:35:56

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:35:16', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '27d148b1-c036-469c-b82a-25bed34c24e7'	System	24 Aug 2020 20:35:56
User entered 'None (0)'	System	24 Aug 2020 20:35:56

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:35:22', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '27d148b1-c036-469c-b82a-25bed34c24e7'	System	24 Aug 2020 20:35:56
User entered 'None (0)'	System	24 Aug 2020 20:35:56

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:35:27', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '27d148b1-c036-469c-b82a-25bed34c24e7'	System	24 Aug 2020 20:35:56
User entered 'None (0)'	System	24 Aug 2020 20:35:56

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-24T15:35:30', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '27d148b1-c036-469c-b82a-25bed34c24e7'	System	24 Aug 2020 20:35:56
User entered 'None (0)'	System	24 Aug 2020 20:35:56

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

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 (82cbad1a1791eaaf)', Time: '2020-08-24T15:35:36', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '27d148b1-c036-469c-b82a-25bed34c24e7'	System	24 Aug 2020 20:35:56
User entered 'No (N)'	System	24 Aug 2020 20:35:56

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:35:46', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '27d148b1-c036-469c-b82a-25bed34c24e7'	System	24 Aug 2020 20:35:56
User entered '24 Aug 2020 15:35'	System	24 Aug 2020 20:35:56

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 15:18'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 17:48'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-24T20:26:44', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'e4c42146-feaf-43eb-9163-ebd734977334'	System	25 Aug 2020 01:29:09
User entered 'None (0)'	System	25 Aug 2020 01:29:09

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:26:55', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'e4c42146-feaf-43eb-9163-ebd734977334'	System	25 Aug 2020 01:29:09
User entered 'No interference with activity (1)'	System	25 Aug 2020 01:29:09

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:27:02', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'e4c42146-feaf-43eb-9163-ebd734977334'	System	25 Aug 2020 01:29:09
User entered 'None (0)'	System	25 Aug 2020 01:29:09

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:27:13', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'e4c42146-feaf-43eb-9163-ebd734977334'	System	25 Aug 2020 01:29:09
User entered 'None (0)'	System	25 Aug 2020 01:29:09

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:27:24', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'e4c42146-feaf-43eb-9163-ebd734977334'	System	25 Aug 2020 01:29:09
User entered 'None (0)'	System	25 Aug 2020 01:29:09

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-24T20:27:34', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'e4c42146-feaf-43eb-9163-ebd734977334'	System	25 Aug 2020 01:29:09
User entered 'None (0)'	System	25 Aug 2020 01:29:09

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

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 (82cbad1a1791eaaf)', Time: '2020-08-24T20:28:48', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'e4c42146-feaf-43eb-9163-ebd734977334'	System	25 Aug 2020 01:29:09
User entered 'No (N)'	System	25 Aug 2020 01:29:09

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:29:04', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'e4c42146-feaf-43eb-9163-ebd734977334'	System	25 Aug 2020 01:29:09
User entered '24 Aug 2020 20:29'	System	25 Aug 2020 01:29:09

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 18:43'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 2'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:38:12', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '50496003-b7f8-4a4b-a079-3e93b7b3742d'	System	25 Aug 2020 17:39:12
User entered 'None (0)'	System	25 Aug 2020 17:39:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-25T12:38:22', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '50496003-b7f8-4a4b-a079-3e93b7b3742d'	System	25 Aug 2020 17:39:12
User entered 'No interference with activity (1)'	System	25 Aug 2020 17:39:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-25T12:38:31', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '50496003-b7f8-4a4b-a079-3e93b7b3742d'	System	25 Aug 2020 17:39:12
User entered 'None (0)'	System	25 Aug 2020 17:39:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-25T12:38:38', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '50496003-b7f8-4a4b-a079-3e93b7b3742d'	System	25 Aug 2020 17:39:12
User entered 'None (0)'	System	25 Aug 2020 17:39:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:38:41', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '50496003-b7f8-4a4b-a079-3e93b7b3742d'	System	25 Aug 2020 17:39:12
User entered 'None (0)'	System	25 Aug 2020 17:39:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-25T12:38:44', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '50496003-b7f8-4a4b-a079-3e93b7b3742d'	System	25 Aug 2020 17:39:12
User entered 'None (0)'	System	25 Aug 2020 17:39:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:56

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 (82cbad1a1791eaaf)', Time: '2020-08-25T12:38:50', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '50496003-b7f8-4a4b-a079-3e93b7b3742d'	System	25 Aug 2020 17:39:12
User entered 'No (N)'	System	25 Aug 2020 17:39:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-25T12:39:09', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '50496003-b7f8-4a4b-a079-3e93b7b3742d'	System	25 Aug 2020 17:39:12
User entered '25 Aug 2020 12:39'	System	25 Aug 2020 17:39:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 3'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-26T13:18:38', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1e3b00e7-2c41-4ba1-840e-9767d697d87a'	System	26 Aug 2020 18:19:17
User entered 'None (0)'	System	26 Aug 2020 18:19:17

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-26T13:18:48', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1e3b00e7-2c41-4ba1-840e-9767d697d87a'	System	26 Aug 2020 18:19:17
User entered 'None (0)'	System	26 Aug 2020 18:19:17

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-26T13:18:52', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1e3b00e7-2c41-4ba1-840e-9767d697d87a'	System	26 Aug 2020 18:19:17
User entered 'None (0)'	System	26 Aug 2020 18:19:17

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-26T13:18:55', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1e3b00e7-2c41-4ba1-840e-9767d697d87a'	System	26 Aug 2020 18:19:17
User entered 'None (0)'	System	26 Aug 2020 18:19:17

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-26T13:18:58', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1e3b00e7-2c41-4ba1-840e-9767d697d87a'	System	26 Aug 2020 18:19:17
User entered 'None (0)'	System	26 Aug 2020 18:19:17

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:19:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1e3b00e7-2c41-4ba1-840e-9767d697d87a'	System	26 Aug 2020 18:19:17
User entered 'None (0)'	System	26 Aug 2020 18:19:17

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:56

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 (82cbad1a1791eaaaf)', Time: '2020-08-26T13:19:04', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1e3b00e7-2c41-4ba1-840e-9767d697d87a'	System	26 Aug 2020 18:19:17
User entered 'No (N)'	System	26 Aug 2020 18:19:17

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:19:15', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1e3b00e7-2c41-4ba1-840e-9767d697d87a'	System	26 Aug 2020 18:19:17
User entered '26 Aug 2020 13:19'	System	26 Aug 2020 18:19:17

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 4'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-27T12:28:40', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '492cea4b-b6c0-4373-b198-3214b99ee985'	System	27 Aug 2020 17:29:08
User entered 'None (0)'	System	27 Aug 2020 17:29:08

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-27T12:28:43', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '492cea4b-b6c0-4373-b198-3214b99ee985'	System	27 Aug 2020 17:29:08
User entered 'None (0)'	System	27 Aug 2020 17:29:08

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-27T12:28:46', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '492cea4b-b6c0-4373-b198-3214b99ee985'	System	27 Aug 2020 17:29:08
User entered 'None (0)'	System	27 Aug 2020 17:29:08

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-27T12:28:49', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '492cea4b-b6c0-4373-b198-3214b99ee985'	System	27 Aug 2020 17:29:08
User entered 'None (0)'	System	27 Aug 2020 17:29:08

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-27T12:28:51', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '492cea4b-b6c0-4373-b198-3214b99ee985'	System	27 Aug 2020 17:29:08
User entered 'None (0)'	System	27 Aug 2020 17:29:08

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-27T12:28:54', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '492cea4b-b6c0-4373-b198-3214b99ee985'	System	27 Aug 2020 17:29:08
User entered 'None (0)'	System	27 Aug 2020 17:29:08

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:56

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 (82cbad1a1791eaaf)', Time: '2020-08-27T12:28:57', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '492cea4b-b6c0-4373-b198-3214b99ee985'	System	27 Aug 2020 17:29:08
User entered 'No (N)'	System	27 Aug 2020 17:29:08

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-27T12:29:04', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '492cea4b-b6c0-4373-b198-3214b99ee985'	System	27 Aug 2020 17:29:08
User entered '27 Aug 2020 12:29'	System	27 Aug 2020 17:29:08

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 5'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:10:16', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '4a8d92ac-12f1-45ce-834e-ef783d262947'	System	28 Aug 2020 17:10:48
User entered 'None (0)'	System	28 Aug 2020 17:10:48

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-28T12:10:19', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '4a8d92ac-12f1-45ce-834e-ef783d262947'	System	28 Aug 2020 17:10:48
User entered 'None (0)'	System	28 Aug 2020 17:10:48

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-28T12:10:21', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '4a8d92ac-12f1-45ce-834e-ef783d262947'	System	28 Aug 2020 17:10:48
User entered 'None (0)'	System	28 Aug 2020 17:10:48

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:10:23', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '4a8d92ac-12f1-45ce-834e-ef783d262947'	System	28 Aug 2020 17:10:48
User entered 'None (0)'	System	28 Aug 2020 17:10:48

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:10:25', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '4a8d92ac-12f1-45ce-834e-ef783d262947'	System	28 Aug 2020 17:10:48
User entered 'None (0)'	System	28 Aug 2020 17:10:48

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-28T12:10:27', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '4a8d92ac-12f1-45ce-834e-ef783d262947'	System	28 Aug 2020 17:10:48
User entered 'None (0)'	System	28 Aug 2020 17:10:48

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:56

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 (82cbad1a1791eaaf)', Time: '2020-08-28T12:10:31', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '4a8d92ac-12f1-45ce-834e-ef783d262947'	System	28 Aug 2020 17:10:48
User entered 'No (N)'	System	28 Aug 2020 17:10:48

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:10:41', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '4a8d92ac-12f1-45ce-834e-ef783d262947'	System	28 Aug 2020 17:10:48
User entered '28 Aug 2020 12:10'	System	28 Aug 2020 17:10:48

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 6'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:17:57', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '9c87bf2c-d9e0-45eb-8395-66957abf413d'	System	29 Aug 2020 17:18:42
User entered 'None (0)'	System	29 Aug 2020 17:18:42

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:18:01', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '9c87bf2c-d9e0-45eb-8395-66957abf413d'	System	29 Aug 2020 17:18:42
User entered 'None (0)'	System	29 Aug 2020 17:18:42

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:18:04', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '9c87bf2c-d9e0-45eb-8395-66957abf413d'	System	29 Aug 2020 17:18:42
User entered 'None (0)'	System	29 Aug 2020 17:18:42

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:18:07', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '9c87bf2c-d9e0-45eb-8395-66957abf413d'	System	29 Aug 2020 17:18:42
User entered 'None (0)'	System	29 Aug 2020 17:18:42

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:18:10', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '9c87bf2c-d9e0-45eb-8395-66957abf413d'	System	29 Aug 2020 17:18:42
User entered 'None (0)'	System	29 Aug 2020 17:18:42

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-29T12:18:12', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '9c87bf2c-d9e0-45eb-8395-66957abf413d'	System	29 Aug 2020 17:18:42
User entered 'None (0)'	System	29 Aug 2020 17:18:42

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:56

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 (82cbad1a1791eaaf)', Time: '2020-08-29T12:18:25', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '9c87bf2c-d9e0-45eb-8395-66957abf413d'	System	29 Aug 2020 17:18:42
User entered 'No (N)'	System	29 Aug 2020 17:18:42

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:18:34', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '9c87bf2c-d9e0-45eb-8395-66957abf413d'	System	29 Aug 2020 17:18:42
User entered '29 Aug 2020 12:18'	System	29 Aug 2020 17:18:42

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 7'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-30T12:24:25', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c6820e91-f606-4223-9593-60da0d3c930e'	System	30 Aug 2020 17:24:51
User entered 'None (0)'	System	30 Aug 2020 17:24:51

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:24:28', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c6820e91-f606-4223-9593-60da0d3c930e'	System	30 Aug 2020 17:24:51
User entered 'None (0)'	System	30 Aug 2020 17:24:51

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-30T12:24:30', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c6820e91-f606-4223-9593-60da0d3c930e'	System	30 Aug 2020 17:24:51
User entered 'None (0)'	System	30 Aug 2020 17:24:51

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:24:33', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c6820e91-f606-4223-9593-60da0d3c930e'	System	30 Aug 2020 17:24:51
User entered 'None (0)'	System	30 Aug 2020 17:24:51

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-30T12:24:35', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c6820e91-f606-4223-9593-60da0d3c930e'	System	30 Aug 2020 17:24:51
User entered 'None (0)'	System	30 Aug 2020 17:24:51

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2020-08-30T12:24:38', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c6820e91-f606-4223-9593-60da0d3c930e'	System	30 Aug 2020 17:24:51
User entered 'None (0)'	System	30 Aug 2020 17:24:51

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:56

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 (82cbad1a1791eaaaf)', Time: '2020-08-30T12:24:41', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c6820e91-f606-4223-9593-60da0d3c930e'	System	30 Aug 2020 17:24:51
User entered 'No (N)'	System	30 Aug 2020 17:24:51

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2020-08-30T12:24:49', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c6820e91-f606-4223-9593-60da0d3c930e'	System	30 Aug 2020 17:24:51
User entered '30 Aug 2020 12:24'	System	30 Aug 2020 17:24:51

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 20:15:12

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:59:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	31 Aug 2020 23:29:46

US3362244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Crystal Rowell (b) (4) (b) (4)	31 Aug 2020 23:29:46

US3362244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Crystal Rowell (b) (4) (b) (4)	31 Aug 2020 23:29:46

US3362244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	31 Aug 2020 23:29:46

US3362244

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	31 Aug 2020 23:45:13

US3362244

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Aug 2020 23:45:13

US3362244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 22:32:29

US3362244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '08 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 22:32:29

US3362244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Sep 2020 22:32:29

US3362244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 22:32:29

US3362244

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 22:33:07

US3362244

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Sep 2020 22:33:07

US3362244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 17:03:57

US3362244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 17:03:57

US3362244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 17:03:57

US3362244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 17:03:57

US3362244

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 17:04:01

US3362244

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 17:04:01

US3362244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 21:52:34

US3362244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 21:52:34

US3362244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	23 Sep 2020 21:52:34

US3362244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:56

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	23 Sep 2020 21:52:34

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '14:20'	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 14:20'	System	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.5' C	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '90'	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '110'	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '75'	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:59:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	26 Sep 2020 20:32:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	26 Sep 2020 20:32:43
User entered '23 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Sep 2020 20:32:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).		26 Sep 2020 20:32:43
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Sep 2020 21:54:47
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Sep 2020 20:32:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).		26 Sep 2020 20:32:43
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Sep 2020 21:54:47
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Sep 2020 20:32:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).		26 Sep 2020 20:32:43
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Sep 2020 21:54:47
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Sep 2020 20:32:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).		26 Sep 2020 20:32:43
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Sep 2020 21:54:47
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Sep 2020 20:32:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).		26 Sep 2020 20:32:43
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Sep 2020 21:54:47
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Sep 2020 20:32:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).		26 Sep 2020 20:32:43
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Sep 2020 21:54:47
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:59:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 21:54:47

US3362244

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:56

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 20:33:48

US3362244

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:56

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 20:33:48

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 20:35:10

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

If No, reason not given

Audit	User	Time (GMT)
User entered 'Withdrawal of Consent by Participant (WITHDRAWAL OF CONSENT)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	02 Oct 2020 19:14:37
User entered 'Other (OTHER)'	Amy Thomassie (b) (4)	26 Sep 2020 20:35:10

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Thank you for your response. However, please update forms as fracture and/or surgery information is not present. Thank you' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 20:10:04
Query 'Per CDM: Thank you for your response. However, please update forms as fracture and/or surgery information is not present. Thank you' answered with 'pending medical records. Will update as soon as recieved.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 22:26:52
User opened query 'Per CDM: Thank you for your response. However, please update forms as fracture and/or surgery information is not present. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:40:17
User closed query 'Per CDM: Please complete applicable AE form for "severe elbow fracture" and dosing discontinuation form if applicable. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:36:48
Query 'Per CDM: Please complete applicable AE form for "severe elbow fracture" and dosing discontinuation form if applicable. Thank you.' answered with 'updated ' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:14:44
User entered 'patient declined due to orthopedic surgery being needed' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:14:37
User opened query 'Per CDM: Please complete applicable AE form for "severe elbow fracture" and dosing discontinuation form if applicable. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 14:54:19
User entered 'participant has severe elbow fracture with surgery pending. participant declined vaccination.'	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 20:35:10

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 20:35:10

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 20:35:10

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 20:35:10

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 20:35:10

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered empty.	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 20:35:10

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 20:35:10

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 20:35:10

US3362244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:56

Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 20:35:46

US3362244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 20:35:46

US3362244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:35'	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 20:35:46

US3362244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 14:35'	System	26 Sep 2020 20:35:46

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:59:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 20:36:03

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:56

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amy Thomassie (b) (4)	26 Sep 2020 20:36:03

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 20:36:03

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '14:42'	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 20:36:03

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '23 Sep 2020 14:42'	System	26 Sep 2020 20:36:03

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:56

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amy Thomassie (b) (4)	26 Sep 2020 20:36:03

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 20:36:03

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 20:36:03

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 20:36:03

US3362244

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amy Thomassie (b) (4) (b) (4)	26 Sep 2020 20:36:17

US3362244

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 20:36:17

US3362244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:39:42

US3362244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:39:42

US3362244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:39:42

US3362244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:39:42

US3362244

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:39:46

US3362244

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Oct 2020 19:39:46

US3362244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 22:56:56

US3362244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '07 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 22:56:56

US3362244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 22:56:56

US3362244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:56:56

US3362244

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 22:57:00

US3362244

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Oct 2020 22:57:00

US3362244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 22:57:18

US3362244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 22:57:18

US3362244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 22:57:18

US3362244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:57:18

US3362244

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 22:57:22

US3362244

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Oct 2020 22:57:22

US3362244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 19:54:17

US3362244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 19:54:17

US3362244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:56

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 19:54:17

US3362244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:59:56

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	12 Nov 2020 19:54:17

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 19:55:22

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 19:55:22

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '12:38'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 19:55:22

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '28 Oct 2020 12:38'	System	12 Nov 2020 19:55:22

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.9' C	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 19:55:22

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 19:55:22

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 19:55:22

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '90'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 19:55:22

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Nov 2020 19:55:22

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '18'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 19:55:22

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Nov 2020 19:55:22

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '127'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 19:55:22

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Nov 2020 19:55:22

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '90'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 19:55:22

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:59:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Nov 2020 19:55:22

US3362244

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:56

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 19:55:30

US3362244

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:59:56

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 19:55:30

US3362244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 19:55:51

US3362244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 19:55:51

US3362244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:50'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 19:55:51

US3362244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '28 Oct 2020 12:50'	System	12 Nov 2020 19:55:51

US3362244

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 19:55:55

US3362244

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 19:55:55

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 64'	System	24 Aug 2020 20:15:12

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[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 (82cbad1a1791eaaf)', Time: '2020-10-26T13:02:17', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '027ae8be-5339-4266-9394-f78f0d8b07ae'	System	26 Oct 2020 18:03:34
User entered 'Yes (Y)'	System	26 Oct 2020 18:03:34

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Have you been exposed to someone with 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 (82cbad1a1791eaaaf)', Time: '2020-10-26T13:02:27', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '027ae8be-5339-4266-9394-f78f0d8b07ae'	System	26 Oct 2020 18:03:34
User entered 'No (N)'	System	26 Oct 2020 18:03:34

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[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 (82cbad1a1791eaaaf)', Time: '2020-10-26T13:02:33', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '027ae8be-5339-4266-9394-f78f0d8b07ae'	System	26 Oct 2020 18:03:34
User entered 'No (N)'	System	26 Oct 2020 18:03:34

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[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 (82cbad1a1791eaaf)', Time: '2020-10-26T13:02:45', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '027ae8be-5339-4266-9394-f78f0d8b07ae'	System	26 Oct 2020 18:03:34
User entered 'Yes (Y)'	System	26 Oct 2020 18:03:34

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Please 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 (82cbad1a1791eaaf)', Time: '2020-10-26T13:02:57', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '027ae8be-5339-4266-9394-f78f0d8b07ae'	System	26 Oct 2020 18:03:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Oct 2020 18:03:34

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-10-26T13:03:21', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '027ae8be-5339-4266-9394-f78f0d8b07ae'	System	26 Oct 2020 18:03:34
User entered '26 Oct 2020 13:03:21'	System	26 Oct 2020 18:03:34

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 20:15:12

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered 'Day 71'	System	24 Aug 2020 20:15:12

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[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 (82cbad1a1791eaaf)', Time: '2020-10-31T09:18:53', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'b39bd4d8-8405-4ac1-97bb-84a1330ea106'	System	31 Oct 2020 14:19:22
User entered 'No (N)'	System	31 Oct 2020 14:19:22

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

Have you been exposed to someone with 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 (82cbad1a1791eaaaf)', Time: '2020-10-31T09:19:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'b39bd4d8-8405-4ac1-97bb-84a1330ea106'	System	31 Oct 2020 14:19:22
User entered 'No (N)'	System	31 Oct 2020 14:19:22

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-10-31T09:19:18', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'b39bd4d8-8405-4ac1-97bb-84a1330ea106'	System	31 Oct 2020 14:19:22
User entered '31 Oct 2020 09:19:18'	System	31 Oct 2020 14:19:22

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 20:15:12

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:15:12
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 20:15:12

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '21 Oct 2020 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '25 Oct 2020 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '28 Oct 2020 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '01 Nov 2020 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '04 Nov 2020 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '08 Nov 2020 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '11 Nov 2020 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '15 Nov 2020 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:55:21

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:59:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:55:21
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:55:21

US3362244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 22:20:57

US3362244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '19 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 22:20:57

US3362244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Nov 2020 22:20:57

US3362244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:59:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 22:20:57

US3362244

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 22:21:04

US3362244

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:59:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 22:21:04

US3362244

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:59:56

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:53:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	02 Oct 2020 19:16:29
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 19:12:17

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Coxarthrosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 04:15:50
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 04:15:50
Data point term sent to Coder	System	02 Oct 2020 19:19:01
User entered 'worsening of left hip pain/arthritis'	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:18:55

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:18:55

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:18:55

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:18:55

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '08 Sep 2020'	Crystal Rowell (b) (4)	02 Oct 2020 19:18:55
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:18:55

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:18:55

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:51:25
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	02 Oct 2020 19:18:55

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '11 Nov 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:51:25
User entered empty.	(b) (4)	
	Crystal Rowell (b) (4)	02 Oct 2020 19:18:55
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4)	02 Oct 2020 19:18:55
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 19:18:55

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:18:55

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'No (N)'	Crystal Rowell (b) (4)	02 Oct 2020 19:18:55
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:18:55

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4)	02 Oct 2020 19:18:55
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:18:55

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:18:55

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4)	02 Oct 2020 19:18:55
	(b) (4)	

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:18:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4)	02 Oct 2020 19:18:55
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4)	02 Oct 2020 19:18:55
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:18:55

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:18:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Not Related (NOT RELATED)'	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:18:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Not Related (NOT RELATED)'	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:18:55

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User closed query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:47:12
Query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' answered with 'updated' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	19 Nov 2020 13:05:35
User opened query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 22:44:03
User closed query 'Per CDM re-query: Thank you for your answer. Please review and clarify "Dosing discontinuation" start date because AE started on 08Sep2020, Visit 2 was 23Sep2020 and Withdrawn was 15sep2020. Please clarify and review if this date is correct. Thank you!' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 11:49:21
Query 'Per CDM re-query: Thank you for your answer. Please review and clarify "Dosing discontinuation" start date because AE started on 08Sep2020, Visit 2 was 23Sep2020 and Withdrawn was 15sep2020. Please clarify and review if this date is correct. Thank you!' answered with 'Please clarify where you are seeing 15SEP2020 as discontinuation/withdrawn date.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 22:11:54
User opened query 'Per CDM re-query: Thank you for your answer. Please review and clarify "Dosing discontinuation" start date because AE started on 08Sep2020, Visit 2 was 23Sep2020 and Withdrawn was 15sep2020. Please clarify and review if this date is correct. Thank you!' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 08:26:49
User closed query 'Per CDM: "Action taken with investigational product" is answered as "Investigational product withdrawn", however no "Dosing discontinuation" is entered. Please consider entering proper "End of Study" forms. Thank you!' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 08:26:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per CDM: "Action taken with investigational product" is answered as "Investigational product withdrawn", however no "Dosing discontinuation" is entered. Please consider entering proper "End of Study" forms. Thank you!' answered with 'applicable EOS forms have been updated' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 16:10:31
User opened query 'Per CDM: "Action taken with investigational product" is answered as "Investigational product withdrawn", however no "Dosing discontinuation" is entered. Please consider entering proper "End of Study" forms. Thank you!' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 13:17:32
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Crystal Rowell (b) (4)	02 Oct 2020 19:18:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4)	02 Oct 2020 19:18:55
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '1'	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:18:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Response noted, please leave this query open and update when data becomes available or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 04:26:38
Query 'Per CDM: Response noted, please leave this query open and update when data becomes available or comment accordingly. ' answered with 'con procedure noted on 29Sep2020' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 16:43:18
User opened query 'Per CDM: Response noted, please leave this query open and update when data becomes available or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 21:03:37
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 21:03:37
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'pending medical records' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:37:24
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 03:48:56
User entered 'I'	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:18:55

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:51:25
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Crystal Rowell (b) (4)	02 Oct 2020 19:18:55

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:18:55

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	02 Oct 2020 19:18:55

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Oct 2020 19:18:55

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:59:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Oct 2020 19:18:55

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:24
User entered 'USA-US112-2020-mRNA-1273-P301000006'	System	29 Oct 2020 18:59:17
User entered 'New'	(b) (4), (b) (6)	29 Oct 2020 18:59:17

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Postoperative abscess, LLT: Postoperative abscess - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 00:51:45
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 00:51:45
Data point term sent to Coder	System	30 Oct 2020 18:58:23
Coding entries removed.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 18:58:03
User entered 'Post operative intra-abdominal aBSCESS' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 18:58:03
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Bone and joint infections, PT: Joint abscess, LLT: Joint abscess - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:54:59
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:54:59
Data point term sent to Coder	System	16 Oct 2020 18:42:15
User entered 'LEFT HIP ABSCESS'	(b) (4), (b) (6) (b) (4)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '12 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:14:57
	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	28 Oct 2020 21:10:35
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:42:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 17:29:45
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' answered with 'Patient is receiving outpatient antibiotics ' (Site from Safety).	Crystal Rowell (b) (4)	10 Nov 2020 21:07:42
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 13:57:50
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 20:17:57
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'ok, will update' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 19:57:11
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:35:12
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	28 Oct 2020 21:10:35
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	28 Oct 2020 21:10:35
User entered empty; reason for change Data Entry Error	Crystal Rowell (b) (4)	28 Oct 2020 21:10:35

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	28 Oct 2020 21:08:20
User entered '13 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 18:42:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:42:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Grade 4 (Grade 4)' reason for change:	Crystal Rowell (b) (4)	28 Oct 2020 21:08:20
Data Entry Error	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	28 Oct 2020 21:10:13
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	28 Oct 2020 21:08:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	28 Oct 2020 21:08:20
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		28 Oct 2020 21:10:13
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		28 Oct 2020 21:10:13
User entered '1' reason for change: Data Entry Error Crystal Rowell	(b) (4)	28 Oct 2020 21:10:13
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	28 Oct 2020 21:08:20
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:42:13

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '12 Oct 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	28 Oct 2020 21:08:20
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:42:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '20 Oct 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	28 Oct 2020 21:08:20
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	28 Oct 2020 21:08:20
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:42:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:42:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:42:13

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 18:42:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 18:42:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 18:42:48
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 18:42:13
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:42:13

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 18:42:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 18:42:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 18:42:48
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 18:42:13
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 18:42:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 18:42:48
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 18:42:48
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 18:42:13
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'I'	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'I'	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:36:30
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	28 Oct 2020 21:08:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the dates and results for the MRI and fluid cultures mentioned in medical records. If not available, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:15:59
User opened query 'PV Query: CT abdomen and pelvis revealed new, irregular consolidative changes in the left lower lobe suspicious for pneumonia. Was this considered an additional AE/SAE? Please complete eCRF as appropriate if yes.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:15:41
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 17:29:38
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)	11 Nov 2020 17:29:32
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'records have been emailed, where are we to capture requested units and reference ranges ?' (Site from Safety).	Crystal Rowell (b) (4)	10 Nov 2020 23:06:43
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'medical records emailed' (Site from Safety).	Crystal Rowell (b) (4)	10 Nov 2020 23:05:47
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:39:58

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Narrative](#)

Audit	User	Time (GMT)
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)	06 Nov 2020 17:37:31
User entered 'subject had a planned procedure for repair of left pubic rami due to chronic/worsening arthritis. Procedure went well initially, however abscess developed and required inpatient hospitalization, subject notified staff on 28Oct2020 regarding inpatient treatment' reason for change: Data Entry Error	Crystal Rowell (b) (4)	28 Oct 2020 21:08:20
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 21:08:20
User entered '0'	System	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Oct 2020 18:42:13

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:59:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Oct 2020 21:08:20

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:02:22
User entered	(b) (4), (b) (6)	02 Nov 2020 15:02:07
'USA-US112-2020-mRNA-1273-P301000006'		

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Axillary vein thrombosis, LLT: Axillary vein thrombosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:45:45
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:45:45
User closed query 'PV Query: The event term 'right axillary and brachial deep vein thrombosis' contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 19:48:26
Data point term sent to Coder	System	11 Nov 2020 17:43:32
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	11 Nov 2020 17:43:06
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'updated ' (Site from System).	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:43:06
Query 'PV Query: The event term 'right axillary and brachial deep vein thrombosis' contains multiple event terms. Please consider separating them into separate events.' answered with 'updated ' (Site from Safety).	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:42:59
Data point term sent to Coder	System	11 Nov 2020 17:33:06
User entered 'RIGHT AXILLARY DEEP VEIN THROMBOSIS' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:32:16
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:43:32
User opened query 'PV Query: The event term 'right axillary and brachial deep vein thrombosis' contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:33:55
Data point term sent to Coder	System	30 Oct 2020 19:04:37
User entered 'Right axillary and brachial deep vein thrombosis'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Oct 2020 19:03:48
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '19 Oct 2020'	Crystal Rowell (b) (4)	30 Oct 2020 19:03:48
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4)	30 Oct 2020 19:03:48
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6) Crystal Rowell (b) (4) (b) (4)	06 Nov 2020 17:34:30 30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4)	30 Oct 2020 19:03:48
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Grade 4 (Grade 4)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Oct 2020 19:03:48
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4)	30 Oct 2020 19:03:48
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '1'	Crystal Rowell (b) (4)	30 Oct 2020 19:03:48
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		30 Oct 2020 19:04:05
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		30 Oct 2020 19:04:05
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	30 Oct 2020 19:03:48
User entered '0'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty; reason for change Data Entry Error	Crystal Rowell (b) (4)	30 Oct 2020 19:04:05
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Not Related (NOT RELATED)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Not Related (NOT RELATED)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User closed query 'PV Query: Please confirm action taken. Reported as not applicable for event "post operative intra-abdominal abscess" with onset of 12 Oct 2020, but reported as withdrawn for event "right axillary and brachial deep vein thrombosis" with onset of 19 Oct 2020. Additionally, per day 29 exposure, the subject withdrew consent due to orthopedic surgery needed.' (Site from Safety). Query 'PV Query: Please confirm action taken. Reported as not applicable for event "post operative intra-abdominal abscess" with onset of 12 Oct 2020, but reported as withdrawn for event "right axillary and brachial deep vein thrombosis" with onset of 19 Oct 2020. Additionally, per day 29 exposure, the subject withdrew consent due to orthopedic surgery needed.' answered with 'updated to not applicable as patient withdrew consent for IP prior to AE' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 19:48:32
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	11 Nov 2020 17:42:43
User opened query 'PV Query: Please confirm action taken. Reported as not applicable for event "post operative intra-abdominal abscess" with onset of 12 Oct 2020, but reported as withdrawn for event "right axillary and brachial deep vein thrombosis" with onset of 19 Oct 2020. Additionally, per day 29 exposure, the subject withdrew consent due to orthopedic surgery needed.' (Site from Safety). User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4)	11 Nov 2020 17:42:10
	(b) (4), (b) (6)	06 Nov 2020 17:39:20
	Crystal Rowell (b) (4)	30 Oct 2020 19:03:48
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '1'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:47:03
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 17:41:44
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
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)	11 Nov 2020 19:48:42
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'medical records have been emailed, where do we put lab and diagnostic test results?' (Site from Safety).	Crystal Rowell (b) (4)	11 Nov 2020 17:36:32
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)	06 Nov 2020 17:38:17
User entered 'Subject had PICC line placed post surgery, note to have pain on 10/19/2020 diagnosed with DVT and PICC line removed, on anti-coagulants'	Crystal Rowell (b) (4)	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:59:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 19:03:48

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:04
User entered 'USA-US112-2020-mRNA-1273-P301000007'	System	02 Nov 2020 15:03:44
User entered 'New'	(b) (4), (b) (6)	02 Nov 2020 15:03:44

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 10:58:40
	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Fractures, HLT: Fracture complications, PT: Fracture nonunion, LLT: Fracture nonunion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:55:47
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:55:47
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Pelvic fractures and dislocations, PT: Pelvic fracture, LLT: Pubic rami fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 09:47:52
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 09:47:52
Data point term sent to Coder	System	30 Oct 2020 19:16:56
User entered 'Worsening of anterior left pelvic ring non-union'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Oct 2020 19:16:53
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Oct 2020 19:16:53
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Oct 2020 19:16:53
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '09 Sep 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 19:56:50
User entered '29 Sep 2020'	Crystal Rowell (b) (4)	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'No (N)'	Crystal Rowell (b) (4)	30 Oct 2020 19:16:53
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '05 Oct 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	09 Nov 2020 22:02:20
User entered '5 Oct 2020'	Crystal Rowell (b) (4)	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4)	30 Oct 2020 19:16:53
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Grade 4 (Grade 4)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:17:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 19:17:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Oct 2020 19:17:06
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:16:53
User entered empty.	Crystal Rowell (b) (4)	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4)	30 Oct 2020 19:16:53
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'I'	Crystal Rowell (b) (4)	30 Oct 2020 19:16:53
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '29 Sep 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Oct 2020 19:17:25
User entered '29 Oct 2020'	Crystal Rowell (b) (4)	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User closed query 'Hospital discharge date is prior to Hospital admission date. Please correct. ' (Site from System).	System	30 Oct 2020 19:17:25
Query 'Hospital discharge date is prior to Hospital admission date. Please correct. ' answered by data change (Site from System).	System	30 Oct 2020 19:17:25
User opened query 'Hospital discharge date is prior to Hospital admission date. Please correct. ' (Site from System).	System	30 Oct 2020 19:16:53
User entered '5 Oct 2020'	Crystal Rowell (b) (4)	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4)	30 Oct 2020 19:16:53
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4)	30 Oct 2020 19:16:53
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Not Related (NOT RELATED)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Not Related (NOT RELATED)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	19 Nov 2020 13:05:05
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Crystal Rowell (b) (4)	30 Oct 2020 19:16:53

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4)	30 Oct 2020 19:16:53
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '1'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'I'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:16:53

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User closed query 'PV Query: Please confirm the event of "worsening of anterior left pelvic ring non-union", occurred after the start of the study.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 20:28:22
User closed query 'PV Query: Was the procedure for the repair of anterior left pelvic ring a planned procedure (prior to starting the study)?' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 20:28:19
User closed query 'PV Query: If the worsening of anterior left pelvic ring non-union occurred prior to the start of the study, and the repair of anterior left pelvic was a planned hospitalization, please consider deleting the event. If to remain as a SAE, please explain.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 20:28:15
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 20:27:55
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)	11 Nov 2020 20:27:51
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 20:27:47

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: If the worsening of anterior left pelvic ring non-union occurred prior to the start of the study, and the repair of anterior left pelvic was a planned hospitalization, please consider deleting the event. If to remain as a SAE, please explain.' answered with 'the patient reported worsening hip pain initially and withdrew IP consent, went to ortho for evaluation of worsening hip pain and it was noted that there was worsening of non-union, no complete healing from original injury' (Site from Safety).	Crystal Rowell (b) (4)	11 Nov 2020 17:57:05
Query 'PV Query: Please confirm the event of "worsening of anterior left pelvic ring non-union", occurred after the start of the study.' answered with 'yes, confirmed started after study start' (Site from Safety).	Crystal Rowell (b) (4)	11 Nov 2020 17:53:03
Query 'PV Query: Was the procedure for the repair of anterior left pelvic ring a planned procedure (prior to starting the study)?' answered with 'no, patient reported previous fracture and chronic arthritic pain at study onset' (Site from Safety).	Crystal Rowell (b) (4)	11 Nov 2020 17:52:41
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	Crystal Rowell (b) (4)	11 Nov 2020 17:50:43
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'medical records have been sent to safety, where do we record this information?' (Site from Safety).	Crystal Rowell (b) (4)	11 Nov 2020 17:50:00
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 'per review of medical records and per patient, not done' (Site from Safety).	Crystal Rowell (b) (4)	11 Nov 2020 17:49:27

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: If the worsening of anterior left pelvic ring non-union occurred prior to the start of the study, and the repair of anterior left pelvic was a planned hospitalization, please consider deleting the event. If to remain as a SAE, please explain.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 22:15:57
User opened query 'PV Query: Please confirm the event of "worsening of anterior left pelvic ring non-union", occurred after the start of the study.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 22:15:43
User opened query 'PV Query: Was the procedure for the repair of anterior left pelvic ring a planned procedure (prior to starting the study)?' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 22:15:36
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 22:15:27
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)	09 Nov 2020 22:15:21
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 22:15:16
User entered 'patient had planned procedure for repair of anterior left pelvic ring, did not disclose hospitalization.'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Oct 2020 19:17:06

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:59:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 19:16:53

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 19:07:42
User entered 'USA-US112-2020-mRNA-1273-P301000006'	(b) (4), (b) (6)	11 Nov 2020 19:07:38

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep venous thrombosis arm - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 18:11:37
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 18:11:37
Data point term sent to Coder	System	11 Nov 2020 17:45:34
User entered 'right brachial deep vein thrombosis'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 17:45:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 17:45:00
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	11 Nov 2020 17:45:00
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 17:44:43
User entered empty.	Crystal Rowell (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '19 Oct 2020'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: SAE # Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:17:22
	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	11 Nov 2020 17:44:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Grade 4 (Grade 4)'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	11 Nov 2020 17:45:33
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	11 Nov 2020 17:44:43
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '1' reason for change: Data Entry Error	Crystal Rowell (b) (4)	11 Nov 2020 17:45:33
User entered '0'	Crystal Rowell (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Not Related (NOT RELATED)'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Not Related (NOT RELATED)'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Not Applicable (NOT APPLICABLE)'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '1'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:17:36
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Nov 2020 17:48:22
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	11 Nov 2020 17:48:22
User entered 'SUBJECT HAD PICC LINE PLACED POST SURGERY, NOTE TO HAVE PAIN ON 10/19/2020 DIAGNOSED WITH DVT AND PICC LINE REMOVED, ON ANTI-COAGULANTS' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:48:22
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Nov 2020 17:44:43
User entered empty.	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:59:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 17:44:43

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:12:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 22:12:37
Data point term sent to Coder	System	11 Nov 2020 22:11:28
User entered 'diarrhea'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '29 Oct 2020'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 22:22:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 22:22:39
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Nov 2020 22:22:55
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	19 Nov 2020 22:22:55
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Nov 2020 22:22:39
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 22:22:39
User entered '12 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 22:22:39
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4)	11 Nov 2020 22:11:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 22:11:02

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Folder: Adverse Events

Form: Adverse Events (6)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

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Folder: Adverse Events

Form: Adverse Events (6)

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4)	11 Nov 2020 22:11:02
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Not Related (NOT RELATED)'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Not Related (NOT RELATED)'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Not Applicable (NOT APPLICABLE)'	Crystal Rowell (b) (4)	11 Nov 2020 22:11:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '1'	Crystal Rowell (b) (4)	11 Nov 2020 22:11:02
	(b) (4)	

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered '0'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 22:22:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 22:22:55
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Crystal Rowell (b) (4)	11 Nov 2020 22:11:02

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered empty.	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:00:16
User entered 'post antibiotic therapy'	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 22:11:02

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 22:11:02

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:59:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 22:11:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 22:47:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 22:47:50
Data point term sent to Coder	System	19 Nov 2020 22:46:48
User entered 'RASH'	(b) (4), (b) (6) (b) (4)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '11 Sep 2020'	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Severity](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 16:39:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 16:39:04
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 16:39:04
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:46:18
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 16:39:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 16:39:04
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 16:39:04
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:46:18
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 16:39:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 16:39:04
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	20 Nov 2020 16:39:04
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:46:18
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[None](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 22:46:18

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 10:59:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 22:46:18

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User closed query 'Per ETRTR: According to SAE "Worsening of Anterior Left Pelvic Ring Non-union" page, medication was dosed. Please add Medication dosing details for SAE "Worsening of Anterior Left Pelvic Ring Non-union" within ConMeds page, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 21:01:22
Query 'Per ETRTR: According to SAE "Worsening of Anterior Left Pelvic Ring Non-union" page, medication was dosed. Please add Medication dosing details for SAE "Worsening of Anterior Left Pelvic Ring Non-union" within ConMeds page, thanks.' answered with 'this has been updated' (Site from CRA).	Crystal Rowell (b) (4)	12 Nov 2020 15:27:01
User opened query 'Per ETRTR: According to SAE "Worsening of Anterior Left Pelvic Ring Non-union" page, medication was dosed. Please add Medication dosing details for SAE "Worsening of Anterior Left Pelvic Ring Non-union" within ConMeds page, thanks.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:33:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:14:38

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ALENDRONATE SODIUM, PRODUCTSYNONYM: ALENDRONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:16:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:16:35
Data point term sent to Coder	System	25 Aug 2020 15:15:23
User entered 'Alendronate'	(b) (4), (b) (6)	25 Aug 2020 15:15:22

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:15:22

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'Osteoporosis'	(b) (4), (b) (6)	25 Aug 2020 15:15:22

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '70'	(b) (4), (b) (6)	25 Aug 2020 15:15:22

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Aug 2020 15:15:22

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:15:22

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'every week (QS)'	(b) (4), (b) (6)	25 Aug 2020 15:15:22

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:15:22

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Aug 2020 15:15:22

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:15:22

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	(b) (4), (b) (6)	25 Aug 2020 15:15:22

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:15:22

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:15:22

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:15:22

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:15:22

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:15:22

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:15:22

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	25 Aug 2020 15:15:22

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:19:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 15:19:34
Data point term sent to Coder	System	25 Aug 2020 15:18:28
User entered 'Atorvastatin'	(b) (4), (b) (6)	25 Aug 2020 15:17:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:17:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'hyperlipidemia'	(b) (4), (b) (6)	25 Aug 2020 15:17:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '80'	(b) (4), (b) (6)	25 Aug 2020 15:17:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Aug 2020 15:17:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:17:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Aug 2020 15:17:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:17:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Aug 2020 15:17:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:17:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (MH#2=2015). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 10:26:50
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (MH#2=2015). Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated' (Site from DM).	Crystal Rowell (b) (4)	02 Oct 2020 19:40:41
User entered 'UN UNK 2015' reason for change: Data Entry Error	Crystal Rowell (b) (4)	02 Oct 2020 19:40:35
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (MH#2=2015). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 09:59:56
User entered 'un UNK 2013'	(b) (4), (b) (6)	25 Aug 2020 15:17:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 15:17:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:50:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 15:17:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '3 Nov 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:50:13
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 15:17:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 15:17:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:17:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 15:17:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Aug 2020 15:17:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL ARTHRITIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:33:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:33:55
Data point term sent to Coder	System	30 Oct 2020 16:33:18
Coding entries removed.	(b) (4), (b) (6)	30 Oct 2020 16:33:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL ARTHRITIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 22:23:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 22:23:38
Data point term sent to Coder	System	01 Sep 2020 22:22:19
User entered 'tylenol arthritis'	Crystal Rowell (b) (4) (b) (4)	01 Sep 2020 22:21:59

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	01 Sep 2020 22:21:59

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update indication as appropriate and ensure update is reconciled with any corresponding MH/AE entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:48:23
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update indication as appropriate and ensure update is reconciled with any corresponding MH/AE entries, if applicable. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:33:17
User entered 'OSTEOARTHRITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:33:04
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update indication as appropriate and ensure update is reconciled with any corresponding MH/AE entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 09:10:40
User entered 'arthritis'	Crystal Rowell (b) (4) (b) (4)	01 Sep 2020 22:21:59

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Crystal Rowell (b) (4) (b) (4)	01 Sep 2020 22:21:59

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	Crystal Rowell (b) (4) (b) (4)	01 Sep 2020 22:21:59

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	01 Sep 2020 22:21:59

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Crystal Rowell (b) (4) (b) (4)	01 Sep 2020 22:21:59

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	01 Sep 2020 22:21:59

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Crystal Rowell (b) (4) (b) (4)	01 Sep 2020 22:21:59

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	01 Sep 2020 22:21:59

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Crystal Rowell (b) (4) (b) (4)	01 Sep 2020 22:21:59

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Crystal Rowell (b) (4) (b) (4)	01 Sep 2020 22:21:59

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	01 Sep 2020 22:21:59

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	01 Sep 2020 22:21:59

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	01 Sep 2020 22:21:59

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 22:21:59

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 22:21:59

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 22:21:59

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL EXTRA STRENGTH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:36:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 16:36:54
Data point term sent to Coder	System	30 Oct 2020 16:36:20
Coding entries removed.	(b) (4), (b) (6)	30 Oct 2020 16:35:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL EXTRA STRENGTH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 17:09:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 17:09:45
Data point term sent to Coder	System	14 Sep 2020 17:08:38
User entered 'Tylenol Extra Strength'	(b) (4), (b) (6)	14 Sep 2020 17:07:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 17:07:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update indication as appropriate and ensure update is reconciled with any corresponding MH/AE entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:50:06
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update indication as appropriate and ensure update is reconciled with any corresponding MH/AE entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:35:28
User entered 'OSTEOARTHRITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:35:20
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update indication as appropriate and ensure update is reconciled with any corresponding MH/AE entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 09:11:10
User entered 'arthritis'	(b) (4), (b) (6)	14 Sep 2020 17:07:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '325'	(b) (4), (b) (6)	14 Sep 2020 17:07:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Sep 2020 17:07:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 17:07:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Sep 2020 17:07:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 17:07:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Sep 2020 17:07:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 17:07:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '25 Aug 2020'	(b) (4), (b) (6)	14 Sep 2020 17:07:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 17:07:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 17:07:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	(b) (4), (b) (6)	14 Sep 2020 17:07:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: 'Was this medication taken for solicited event' = Yes, however this indication is not listed as one of Solicited events. Please review if response should be updated. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 10:41:03
Query 'Per DM CLR: 'Was this medication taken for solicited event' = Yes, however this indication is not listed as one of Solicited events. Please review if response should be updated. Otherwise, please provide clarification.' answered with 'entry error' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 20:42:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 20:41:50
User opened query 'Per DM CLR: 'Was this medication taken for solicited event' = Yes, however this indication is not listed as one of Solicited events. Please review if response should be updated. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 14:35:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 17:07:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 17:07:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 17:07:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 17:07:39

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 20:03:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 20:03:46
Data point term sent to Coder	System	02 Oct 2020 20:02:38
User entered 'Tramadol'	(b) (4), (b) (6)	02 Oct 2020 20:02:32

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 20:02:32

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'arthritis'	(b) (4), (b) (6)	02 Oct 2020 20:02:32

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '25'	(b) (4), (b) (6)	02 Oct 2020 20:02:32

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Oct 2020 20:02:32

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:02:32

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	(b) (4), (b) (6)	02 Oct 2020 20:02:32

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'every 12 hours'	(b) (4), (b) (6)	02 Oct 2020 20:02:32

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Oct 2020 20:02:32

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:02:32

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'UN Feb 2020'	(b) (4), (b) (6)	02 Oct 2020 20:02:32

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 20:02:32

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:46:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:02:32

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '3 Nov 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:46:19
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:02:32

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:46:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:02:32

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 20:02:32

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 20:02:32

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 20:02:32

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 17:42:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 17:42:35
Data point term sent to Coder	System	11 Nov 2020 17:26:55
User entered 'HYDROCODONE/ACETAMINOPHEN' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:26:07
Data point term sent to Coder	System	11 Nov 2020 17:25:53
Coding entries removed.	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:25:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 07:06:45
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 07:06:45
Data point term sent to Coder	System	02 Oct 2020 20:41:55
User entered 'hydrocodone/actetamenophen'	(b) (4), (b) (6) (b) (4)	02 Oct 2020 20:41:43

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 20:41:43

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'PAIN SECONDARY worsening of anterior left pelvic ring non-union' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:25:00
User entered 'pain secondary to hip fracture'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 20:41:43

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '7.5/325'	(b) (4), (b) (6)	02 Oct 2020 20:41:43

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Oct 2020 20:41:43

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:41:43

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'four times daily (QID)'	(b) (4), (b) (6)	02 Oct 2020 20:41:43

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:41:43

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Oct 2020 20:41:43

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:41:43

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	02 Oct 2020 20:41:43

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 20:41:43

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:45:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:41:43

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '3 Nov 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:45:10
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:41:43

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 20:41:43

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Oct 2020 20:41:43

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 20:41:43

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 20:41:43

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 08:26:42
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 08:26:42
Data point term sent to Coder	System	12 Nov 2020 20:44:54
Coding entries removed.	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:44:03
User entered 'METHYLPREDNISOLONE' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:44:03
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 06:50:38
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 06:50:38
Data point term sent to Coder	System	02 Oct 2020 20:43:58
User entered 'methylprednisilone'	(b) (4), (b) (6) (b) (4)	02 Oct 2020 20:43:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 20:43:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'pain/ hip fracture'	(b) (4), (b) (6)	02 Oct 2020 20:43:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '4'	(b) (4), (b) (6)	02 Oct 2020 20:43:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	02 Oct 2020 20:48:24
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 20:48:24
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	02 Oct 2020 20:43:54
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Oct 2020 20:43:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'dose pack'	(b) (4), (b) (6)	02 Oct 2020 20:43:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	02 Oct 2020 20:43:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

If frequency is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:43:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Oct 2020 20:43:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:43:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '9 Sep 2020'	(b) (4), (b) (6)	02 Oct 2020 20:43:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 20:43:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 20:43:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Sep 2020'	(b) (4), (b) (6)	02 Oct 2020 20:43:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 20:43:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 20:43:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 20:43:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 20:43:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 06:15:39
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 06:15:39
Data point term sent to Coder	System	11 Nov 2020 17:24:53
Coding entries removed.	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:24:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 20:52:49
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 20:52:49
Data point term sent to Coder	System	02 Oct 2020 20:46:00
User entered 'gabapentin'	(b) (4), (b) (6) (b) (4)	02 Oct 2020 20:45:18

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 20:45:18

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'worsening of anterior left pelvic ring non-union' reason for change: Data Entry Error	Crystal Rowell (b) (4)	11 Nov 2020 17:24:31
User entered 'hip pain/fracture'	(b) (4), (b) (6)	02 Oct 2020 20:45:18

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	02 Oct 2020 20:45:18

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	02 Oct 2020 20:45:18

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:45:18

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	(b) (4), (b) (6)	02 Oct 2020 20:45:18

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:45:18

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Oct 2020 20:45:18

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:45:18

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '9 Sep 2020'	(b) (4), (b) (6)	02 Oct 2020 20:45:18

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 20:45:18

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:42:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:45:18

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '3 Nov 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:42:00
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:45:18

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 20:45:18

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Oct 2020 20:45:18

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 20:45:18

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 20:45:18

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:37:18
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:37:18
Data point term sent to Coder	System	02 Oct 2020 20:47:02
User entered 'dulcolax'	(b) (4), (b) (6) (b) (4)	02 Oct 2020 20:46:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 20:46:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'help prevent constipation from pain medication'	(b) (4), (b) (6)	02 Oct 2020 20:46:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 20:46:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 20:49:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 20:49:02
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 20:49:02
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 20:46:49
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:46:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:46:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	02 Oct 2020 20:46:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:46:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	02 Oct 2020 20:46:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:46:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	02 Oct 2020 20:46:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 20:46:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:40:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 20:46:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Oct 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:40:51
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 20:46:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Oct 2020 20:46:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 20:46:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 20:46:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Oct 2020 20:46:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 11:24:12
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 11:24:12
Data point term sent to Coder	System	30 Oct 2020 19:21:07
User entered 'apixaban'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:20:52

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:20:52

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'right axillary and brachial deep vein thrombosis'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:20:52

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:20:52

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:20:52

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:20:52

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:20:52

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:20:52

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:20:52

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:20:52

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:20:52

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

Start date completely unknown

Audit	User	Time (GMT)
User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	30 Oct 2020 19:21:19
User entered '0' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Oct 2020 19:21:19
User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	(b) (4) System	30 Oct 2020 19:20:52
User entered '1'	Crystal Rowell (b) (4)	30 Oct 2020 19:20:52

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:21:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 19:21:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Oct 2020 19:21:19
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:20:52
User entered empty.	Crystal Rowell (b) (4)	30 Oct 2020 19:20:52

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:20:52

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:20:52

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Oct 2020 19:20:52

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 19:20:52

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Oct 2020 19:20:52

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

[Name of Medication](#)

Audit	User	Time (GMT)
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: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:36:37
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 Nov 2020 23:36:37
Data point term sent to Coder	System	11 Nov 2020 17:30:01
Coding entries removed.	Crystal Rowell (b) (4) (b) (4)	11 Nov 2020 17:29:28
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: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 11:18:19
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 11:18:19
Data point term sent to Coder	System	30 Oct 2020 19:24:10
User entered 'diclofenac EC'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:23:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:23:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'left hip pain due to worsening of anterior left pelvic ring non-union' reason for change: Data Entry Error	Crystal Rowell (b) (4)	11 Nov 2020 17:29:28
User entered 'left hip pain'	Crystal Rowell (b) (4)	30 Oct 2020 19:23:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:23:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:23:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:23:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:23:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:23:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:23:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:23:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:23:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:23:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:11:58
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Oct 2020 19:23:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '3 Nov 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:11:58
User entered empty.	Crystal Rowell (b) (4)	30 Oct 2020 19:23:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:23:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 19:23:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 19:23:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 19:23:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOBACTERIALS, ATC: DRUGS FOR TREATMENT OF LEPRA, ATC: DRUGS FOR TREATMENT OF LEPRA, PRODUCT: RIFAMPICIN, PRODUCTSYNONYM: RIFAMPIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 00:59:08
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 00:59:08
Data point term sent to Coder	System	30 Oct 2020 19:26:11
User entered 'Rifampin'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:25:34

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:25:34

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'post operative intra-abdominal abscess'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:25:34

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '300'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:25:34

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:25:34

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:25:34

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:25:34

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:25:34

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:25:34

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:25:34

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:25:34

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:25:34

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:00:45
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	30 Oct 2020 19:25:34

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '3 Nov 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:00:45
User entered empty.	Crystal Rowell (b) (4)	30 Oct 2020 19:25:34

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:25:34

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Oct 2020 19:25:34

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 19:25:34

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Oct 2020 19:25:34

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFRADINE, PRODUCTSYNONYM: ANCEF [CEFADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:59:39
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:59:39
Data point term sent to Coder	System	30 Oct 2020 19:28:16
Data point term sent to Coder	System	30 Oct 2020 19:27:15
User entered 'Ancef'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:26:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:26:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:27:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 19:27:52
User entered 'post operative intra-abdominal abscess' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Oct 2020 19:27:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	30 Oct 2020 19:26:58
	Crystal Rowell (b) (4)	30 Oct 2020 19:26:58
	(b) (4)	

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:27:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 19:27:52
User entered '2' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Oct 2020 19:27:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Oct 2020 19:26:58
User entered empty.	System	30 Oct 2020 19:26:58
	Crystal Rowell (b) (4)	30 Oct 2020 19:26:58
	(b) (4)	

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:27:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 19:27:52
User entered 'g (g)' reason for change: Data Entry Error	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:27:52
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:26:58
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:26:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:26:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:27:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 19:27:52
User entered 'three times daily (TID)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Oct 2020 19:27:52
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:26:58
User entered empty.	Crystal Rowell (b) (4)	30 Oct 2020 19:26:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:26:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:27:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 19:27:52
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Oct 2020 19:27:52
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:26:58
User entered empty.	Crystal Rowell (b) (4)	30 Oct 2020 19:26:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:26:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	30 Oct 2020 19:27:52
User entered '20 Oct 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Oct 2020 19:27:52
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	30 Oct 2020 19:26:58
User entered empty.	Crystal Rowell (b) (4)	30 Oct 2020 19:26:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:26:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:00:04
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:27:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 19:27:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Oct 2020 19:27:52
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:26:58
User entered empty.	Crystal Rowell (b) (4)	30 Oct 2020 19:26:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '3 Nov 2020' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:00:04
User entered empty.	Crystal Rowell (b) (4)	30 Oct 2020 19:26:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:27:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 19:27:52
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Oct 2020 19:27:52
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:26:58
User entered empty.	Crystal Rowell (b) (4)	30 Oct 2020 19:26:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Oct 2020 19:27:52
User entered empty.	System	30 Oct 2020 19:26:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 19:27:52
User entered empty.	System	30 Oct 2020 19:26:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Oct 2020 19:27:52
User entered empty.	System	30 Oct 2020 19:26:58

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 11:15:17
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 11:15:17
Data point term sent to Coder	System	30 Oct 2020 19:30:18
User entered 'ferrous sulfate'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:29:44

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:29:44

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'alpha thalassemia'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:29:44

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '324'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:29:44

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:29:44

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:29:44

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:29:44

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:29:44

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:29:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 19:29:50
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Oct 2020 19:29:50
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:29:44
User entered empty.	Crystal Rowell (b) (4)	30 Oct 2020 19:29:44

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:29:44

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:29:44

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:29:44

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:29:44

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 19:29:44

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:29:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Oct 2020 19:29:54
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	30 Oct 2020 19:29:54
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Oct 2020 19:29:44
User entered empty.	Crystal Rowell (b) (4)	30 Oct 2020 19:29:44

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 19:29:44

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 19:29:44

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Oct 2020 19:29:44

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 20:06:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 20:06:35
Data point term sent to Coder	System	12 Nov 2020 20:05:44
User entered 'Lactated Ringers'	Crystal Rowell (b) (4)	12 Nov 2020 20:04:53

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:04:53

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'IV hydration secondary to post operative intra-abdominal abscess'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:04:53

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:04:53

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:04:53

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:04:53

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:04:53

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:04:53

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:04:53

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:04:53

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:04:53

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:04:53

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:04:53

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:04:53

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:04:53

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 20:04:53

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 20:04:53

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 20:04:53

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: LINEZOLID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 04:36:44
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 04:36:44
Data point term sent to Coder	System	12 Nov 2020 20:15:04
User entered 'linezolid'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:14:26

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:14:26

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'post-operative intrabdominal abscess'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:14:26

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '600'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:14:26

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:14:26

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:14:26

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:14:26

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:14:26

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:14:26

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:14:26

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '4 Nov 2020'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:14:26

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:14:26

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 22:28:45
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:14:26

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 22:28:45
User entered empty.	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:14:26

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:14:26

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Nov 2020 20:14:26

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 20:14:26

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 20:14:26

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: DAPTOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 21:27:37
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 Nov 2020 21:27:37
Data point term sent to Coder	System	12 Nov 2020 20:39:48
User entered 'Daptomycin'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:38:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:38:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'Post operative intrabdominal abscess'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:38:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '420'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:38:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:38:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:38:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:38:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:38:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:38:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:38:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered '9 Nov 2020'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:38:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:38:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:38:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Crystal Rowell (b) (4) (b) (4)	12 Nov 2020 20:38:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 20:38:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 20:38:59
User entered 'No (N)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	12 Nov 2020 20:38:59
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 20:38:49
User entered empty.	Crystal Rowell (b) (4)	12 Nov 2020 20:38:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 20:38:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 20:38:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 20:38:49

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 22:35:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 22:35:50
Data point term sent to Coder	System	19 Nov 2020 22:34:42
User entered 'CALCIUM'	(b) (4), (b) (6) (b) (4)	19 Nov 2020 22:33:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 22:33:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'OSTEOPOROSIS'	(b) (4), (b) (6)	19 Nov 2020 22:33:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	(b) (4), (b) (6)	19 Nov 2020 22:33:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Nov 2020 22:33:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 22:33:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	19 Nov 2020 22:33:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 22:33:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Nov 2020 22:33:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 22:33:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 22:33:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 22:33:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 22:33:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 22:33:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 22:33:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Nov 2020 22:33:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:33:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 22:33:54

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB, PRODUCTSYNONYM: PROLIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 22:38:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 22:38:04
Data point term sent to Coder	System	19 Nov 2020 22:36:43
User entered 'PROLIA'	(b) (4), (b) (6)	19 Nov 2020 22:36:16

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 22:36:16

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'OSTEOPOROSIS'	(b) (4), (b) (6)	19 Nov 2020 22:36:16

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '60'	(b) (4), (b) (6)	19 Nov 2020 22:36:16

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Nov 2020 22:36:16

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 22:36:16

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	(b) (4), (b) (6)	19 Nov 2020 22:36:16

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'EVERY 6 MONTHS'	(b) (4), (b) (6)	19 Nov 2020 22:36:16

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	19 Nov 2020 22:36:16

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 22:36:16

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '05 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 22:36:16

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 22:36:16

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 22:36:16

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '05 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 22:36:16

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 22:36:16

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:36:16

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:36:16

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 10:59:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:36:16

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:59:56

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Query 'Per ETRTR: According to SAE "Worsening of Anterior Left Pelvic Ring Non-union" page, Procedure was performed. Please add Procedures details for SAE "Worsening of Anterior Left Pelvic Ring Non-union" within ConProcedures page, thanks.' answered with 'per query UPDATED ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:01:05
User opened query 'Per ETRTR: According to SAE "Worsening of Anterior Left Pelvic Ring Non-union" page, Procedure was performed. Please add Procedures details for SAE "Worsening of Anterior Left Pelvic Ring Non-union" within ConProcedures page, thanks.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:34:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 18:43:04
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 19:12:24

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:59:56

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 18:44:11

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:59:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'DRAINAGE OF ABSCESS'	(b) (4), (b) (6)	16 Oct 2020 18:44:11

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	16 Oct 2020 18:44:11

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:59:56

If indication is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 18:44:11

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:59:56

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	10 Nov 2020 22:00:54

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:59:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'left pelvic ring fracture nonunion repair'	(b) (4), (b) (6)	10 Nov 2020 22:00:54

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:59:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	10 Nov 2020 22:00:54

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:59:56

If indication is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 22:00:54

US3362244

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:59:56

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PER DMR-Data is entered on dosing discontinuation form. but no data is updated on the End of study/study discontinuation form. Kindly verify and consider to update data accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:21:36
Query 'PER DMR-Data is entered on dosing discontinuation form. but no data is updated on the End of study/study discontinuation form. Kindly verify and consider to update data accordingly. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 22:15:40
User entered '23 Sep 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	14 Oct 2020 22:15:37
User opened query 'PER DMR-Data is entered on dosing discontinuation form. but no data is updated on the End of study/study discontinuation form. Kindly verify and consider to update data accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 08:03:43
User entered '15 Sep 2020'	(b) (4), (b) (6)	08 Oct 2020 16:10:11

US3362244

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:59:56

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4), (b) (6)	08 Oct 2020 16:10:11

US3362244

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User closed query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:44:31
Query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' answered with 'updated ' (Site from DM).	Crystal Rowell (b) (4)	18 Nov 2020 22:10:41
User entered 'AE ID 1' reason for change: Data Entry Error	Crystal Rowell (b) (4)	18 Nov 2020 22:10:31
User opened query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:00:38
User entered 'Worsening of Hip condition caused subject to refuse 2nd vaccine administration'	(b) (4), (b) (6)	08 Oct 2020 16:10:11

US3362244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:59:56

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please be aware that this form should not be completed because subject withdrawn only IP and not the study. Please consider removing data here. Thank you!' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:46:02
Query 'Per CDM: Please be aware that this form should not be completed because subject withdrawn only IP and not the study. Please consider removing data here. Thank you!' answered with 'data removed per query' (Site from DM).	Amy Thomassie (b) (4)	21 Oct 2020 00:15:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 17:09:18
User opened query 'Per CDM: Please be aware that this form should not be completed because subject withdrawn only IP and not the study. Please consider removing data here. Thank you!' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 11:07:45
Query 'Data is required. Please complete.' answered with 'Patient not completely withdrawn from study. Patient only withdrew consent from IP.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 22:22:35
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 22:19:46
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:19:46

US3362244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:59:56

[Reason for discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 07:46:03
Query 'Data is required. Please complete.' answered with 'query above requested data be removed for now' (Site from System).	Amy Thomassie (b) (4)	21 Oct 2020 00:16:03
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 00:15:10
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	21 Oct 2020 00:15:10
User closed query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	16 Oct 2020 21:20:24
User opened query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	14 Oct 2020 22:19:46
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4), (b) (6)	14 Oct 2020 22:19:46

US3362244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:59:56

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

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	21 Oct 2020 00:15:10
User entered 'Patient having surgical procedure one week after 2nd injection was scheduled. Patient elected to withdraw IP and proceed with surgery.Patient only discontinued IP.She is still continuing in the study'	(b) (4), (b) (6)	14 Oct 2020 22:19:46

US3362244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:59:56

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Amy Thomassie (b) (4)	16 Oct 2020 21:20:24
User entered 'Adverse event (ADVERSE EVENT)'	(b) (4), (b) (6)	14 Oct 2020 22:19:46

US3362244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:59:56

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:19:46

US3362244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:59:56

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:19:46

US3362244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:59:56

[Was autopsy performed?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 22:19:46

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'USA-US112-2020-MRNA-1273-P301000006'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Yes (Y)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:21
Un-reviewed for Safety.	System	02 Nov 2020 15:02:07
User entered 'Yes (Y)'	System	02 Nov 2020 15:02:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Yes (Y)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Jordan'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Whatley'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered '5326 O'donovan dr'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'baton rouge'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:21
User entered empty.	System	02 Nov 2020 15:02:07
User entered '5326 O'Donovan Dr Baton Rouge, La 70808'	Crystal Rowell (b) (4)	30 Oct 2020 18:54:16

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered '70808'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:21
User entered 'US'	System	29 Oct 2020 18:59:53

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Nov 2020 19:08:22
User entered '2'	System	02 Nov 2020 15:04:41
User entered '1'	System	29 Oct 2020 18:59:53

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'USA-US112-2020-MRNA-1273-P301000006'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Yes (Y)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:21
Un-reviewed for Safety.	System	02 Nov 2020 15:02:07
User entered 'Yes (Y)'	System	02 Nov 2020 15:02:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Yes (Y)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Jordan'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Whatley'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered '5326 O'donovan dr'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'baton rouge'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:21
User entered empty.	System	02 Nov 2020 15:02:07
User entered '5326 O'Donovan Dr Baton Rouge, La 70808'	Crystal Rowell (b) (4)	30 Oct 2020 18:54:16

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered '70808'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:21
User entered 'US'	System	29 Oct 2020 18:59:53

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Nov 2020 19:08:22
User entered '2'	System	02 Nov 2020 15:04:41
User entered '1'	System	29 Oct 2020 18:59:53

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:59:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
User entered '29/Oct/2020 18:59'	System	29 Oct 2020 18:59:53

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:59:56

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)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:21
User entered 'I'	(b) (4), (b) (6)	29 Oct 2020 18:59:53

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'USA-US112-2020-MRNA-1273-P301000006'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Yes (Y)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:21
Un-reviewed for Safety.	System	02 Nov 2020 15:02:07
User entered 'Yes (Y)'	System	02 Nov 2020 15:02:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Yes (Y)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Jordan'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Whatley'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered '5326 O'donovan dr'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'baton rouge'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:21
User entered empty.	System	02 Nov 2020 15:02:07
User entered '5326 O'Donovan Dr Baton Rouge, La 70808'	Crystal Rowell (b) (4)	30 Oct 2020 18:54:16

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered '70808'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:21
User entered 'US'	System	29 Oct 2020 18:59:53

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Nov 2020 19:08:22
User entered '2'	System	02 Nov 2020 15:04:41
User entered '1'	System	29 Oct 2020 18:59:53

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:59:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
User entered '30/Oct/2020 13:55'	Crystal Rowell (b) (4) (b) (4)	30 Oct 2020 18:55:19

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:59:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 19:07:59
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
User entered '0'	(b) (4), (b) (6)	02 Nov 2020 15:04:41

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'USA-US112-2020-MRNA-1273-P301000006'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Yes (Y)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:21
Un-reviewed for Safety.	System	02 Nov 2020 15:02:07
User entered 'Yes (Y)'	System	02 Nov 2020 15:02:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Yes (Y)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Jordan'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Whatley'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered '5326 O'donovan dr'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'baton rouge'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:21
User entered empty.	System	02 Nov 2020 15:02:07
User entered '5326 O'Donovan Dr Baton Rouge, La 70808'	Crystal Rowell (b) (4)	30 Oct 2020 18:54:16

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered '70808'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:21
User entered 'US'	System	29 Oct 2020 18:59:53

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Nov 2020 19:08:22
User entered '2'	System	02 Nov 2020 15:04:41
User entered '1'	System	29 Oct 2020 18:59:53

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:59:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
User entered '02/Nov/2020 10:04'	System	02 Nov 2020 15:04:41

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:59:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 19:07:59
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
User entered 'I'	(b) (4), (b) (6)	02 Nov 2020 15:04:41

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'USA-US112-2020-MRNA-1273-P301000006'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Yes (Y)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:21
Un-reviewed for Safety.	System	02 Nov 2020 15:02:07
User entered 'Yes (Y)'	System	02 Nov 2020 15:02:07
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Yes (Y)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'No (N)'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Jordan'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'Whatley'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered '5326 O'donovan dr'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered 'baton rouge'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:21
User entered empty.	System	02 Nov 2020 15:02:07
User entered '5326 O'Donovan Dr Baton Rouge, La 70808'	Crystal Rowell (b) (4)	30 Oct 2020 18:54:16

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 18:59:43
User entered '70808'	System	29 Oct 2020 18:59:17

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:26
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:21
User entered 'US'	System	29 Oct 2020 18:59:53

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Nov 2020 19:08:22
User entered '2'	System	02 Nov 2020 15:04:41
User entered '1'	System	29 Oct 2020 18:59:53

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:59:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '11/Nov/2020 19:08'	System	11 Nov 2020 19:08:22

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:59:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 19:08:22

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'USA-US112-2020-MRNA-1273-P301000007'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Yes (Y)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Yes (Y)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Jordan'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Whatley'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered '5326 O'donovan dr'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'baton rouge'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:31:16
Un-reviewed for Safety.	System	10 Nov 2020 16:32:26
User entered empty.	System	10 Nov 2020 16:32:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:31:52
User entered 'Louisiana'	Crystal Rowell (b) (4)	09 Nov 2020 22:01:36

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered '70808'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'US'	System	02 Nov 2020 15:04:41

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Nov 2020 19:29:01
User entered '4'	System	13 Nov 2020 13:41:36
User entered '3'	System	11 Nov 2020 20:31:36
User entered '2'	System	10 Nov 2020 16:32:26
User entered '1'	System	02 Nov 2020 15:05:02

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'USA-US112-2020-MRNA-1273-P301000007'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Yes (Y)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Yes (Y)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Jordan'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Whatley'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered '5326 O'donovan dr'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'baton rouge'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:31:16
Un-reviewed for Safety.	System	10 Nov 2020 16:32:26
User entered empty.	System	10 Nov 2020 16:32:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:31:52
User entered 'Louisiana'	Crystal Rowell (b) (4)	09 Nov 2020 22:01:36

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered '70808'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'US'	System	02 Nov 2020 15:04:41

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Nov 2020 19:29:01
User entered '4'	System	13 Nov 2020 13:41:36
User entered '3'	System	11 Nov 2020 20:31:36
User entered '2'	System	10 Nov 2020 16:32:26
User entered '1'	System	02 Nov 2020 15:05:02

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:59:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
User entered '02/Nov/2020 10:04'	System	02 Nov 2020 15:05:02

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:59:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:31:52
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
User entered 'I'	(b) (4), (b) (6)	02 Nov 2020 15:05:02

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'USA-US112-2020-MRNA-1273-P301000007'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Yes (Y)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Yes (Y)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Jordan'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Whatley'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered '5326 O'donovan dr'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'baton rouge'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:31:16
Un-reviewed for Safety.	System	10 Nov 2020 16:32:26
User entered empty.	System	10 Nov 2020 16:32:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:31:52
User entered 'Louisiana'	Crystal Rowell (b) (4)	09 Nov 2020 22:01:36

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered '70808'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'US'	System	02 Nov 2020 15:04:41

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Nov 2020 19:29:01
User entered '4'	System	13 Nov 2020 13:41:36
User entered '3'	System	11 Nov 2020 20:31:36
User entered '2'	System	10 Nov 2020 16:32:26
User entered '1'	System	02 Nov 2020 15:05:02

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:59:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '10/Nov/2020 11:32'	System	10 Nov 2020 16:32:26

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:59:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:31:16
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 16:32:26

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'USA-US112-2020-MRNA-1273-P301000007'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Yes (Y)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Yes (Y)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Jordan'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Whatley'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered '5326 O'donovan dr'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'baton rouge'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:31:16
Un-reviewed for Safety.	System	10 Nov 2020 16:32:26
User entered empty.	System	10 Nov 2020 16:32:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:31:52
User entered 'Louisiana'	Crystal Rowell (b) (4)	09 Nov 2020 22:01:36

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered '70808'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'US'	System	02 Nov 2020 15:04:41

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Nov 2020 19:29:01
User entered '4'	System	13 Nov 2020 13:41:36
User entered '3'	System	11 Nov 2020 20:31:36
User entered '2'	System	10 Nov 2020 16:32:26
User entered '1'	System	02 Nov 2020 15:05:02

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:59:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '11/Nov/2020 20:31'	System	11 Nov 2020 20:31:36

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:59:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:41:17
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 20:31:36

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'USA-US112-2020-MRNA-1273-P301000007'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Yes (Y)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Yes (Y)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Jordan'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Whatley'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered '5326 O'donovan dr'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'baton rouge'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:31:16
Un-reviewed for Safety.	System	10 Nov 2020 16:32:26
User entered empty.	System	10 Nov 2020 16:32:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:31:52
User entered 'Louisiana'	Crystal Rowell (b) (4)	09 Nov 2020 22:01:36

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered '70808'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'US'	System	02 Nov 2020 15:04:41

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Nov 2020 19:29:01
User entered '4'	System	13 Nov 2020 13:41:36
User entered '3'	System	11 Nov 2020 20:31:36
User entered '2'	System	10 Nov 2020 16:32:26
User entered '1'	System	02 Nov 2020 15:05:02

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:59:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '13/Nov/2020 13:41'	System	13 Nov 2020 13:41:36

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:59:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 19:28:22
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 13:41:36

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'USA-US112-2020-MRNA-1273-P301000007'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Yes (Y)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Yes (Y)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'No (N)'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Jordan'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'Whatley'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered '5326 O'donovan dr'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'baton rouge'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:31:16
Un-reviewed for Safety.	System	10 Nov 2020 16:32:26
User entered empty.	System	10 Nov 2020 16:32:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 16:31:52
User entered 'Louisiana'	Crystal Rowell (b) (4)	09 Nov 2020 22:01:36

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered '70808'	System	02 Nov 2020 15:03:44

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:55:47
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:04:50
User entered 'US'	System	02 Nov 2020 15:04:41

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:59:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	20 Nov 2020 19:29:01
User entered '4'	System	13 Nov 2020 13:41:36
User entered '3'	System	11 Nov 2020 20:31:36
User entered '2'	System	10 Nov 2020 16:32:26
User entered '1'	System	02 Nov 2020 15:05:02

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 10:59:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '20/Nov/2020 19:28'	System	20 Nov 2020 19:29:01

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 10:59:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	20 Nov 2020 19:29:01